THE UNITED REPUBLIC OF TANZANIA

GOVERNMENT NOTICE NO. ……..… published on……..…

THE ENVIRONMENTAL MANAGEMENT ACT
(CAP. 191)

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REGULATIONS

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(Made under Sections 69 and 230(2)(o))

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THE ENVIRONMENTAL MANAGEMENT (BIOSAFETY) REGULATIONS, 2009

PART I
PRELIMINARY PROVISIONS

Regulation Title

PART II
GENERAL PRINCIPLES

PART III
ADMINISTRATION AND INSTITUTIONAL ARRANGEMENTS

SCHEDULES

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PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Environmental Management (Biosafety) Regulations, 2009.

Application

2. These Regulations shall apply to the import, export, deliberate release, confined use, contained use, transit and placing on the market of GMOs and their products.

Interpretation

3. In these Regulations, unless the context requires otherwise-

Cap. 191

"Act" means the Environmental Management Act;

"advance informed agreement" means consent obtained before any activity is undertaken based upon full disclosure of all relevant matters;

"adventitious presence of GMOs" means the thresholds levels set by the competent authority as contemplated by Regulation 45;

"applicant" means a person or country submitting an application for approval to make, import, export, use under containment, use under confinement, release or place on the market any genetically modified organism or any product of any genetically modified organism;

"Biosafety Clearing House" means the information exchange mechanism

established under Article 20 of the Cartagena Protocol of Biosafety;

"confined use" means

"contained use" means any operation in which GMOs or their products are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and, or biological barriers, to effectively limit their contact with, and their impact on, the general population, biological diversity and the external environment;

"Competent Authority" means the ministerial competent authority designated as such under Regulation 11;

"deliberate release" or "release" means any intentional introduction into the environment, including any production or use that is not contained use, of GMOs or products thereof; **this includes releases for: commercial purposes, remediation, research purposes in field experiments, use of GMOs or products thereof in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation, disposal of waste containing GMOs or their products and transport of GMOs or their products;**

"gene technology" means and refers to techniques that involve the isolation, characterisation, modification and introduction of DNA into living cells or viruses; Cell technology refers to techniques for the production of living cells with new combinations of genetic material by the fusion of two or more cells;

"genetically modified organism (GMO)" means any biological entity capable of replication or transfer of genetic information, and includes plants, animals, synthetic organisms, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, viruses, and plasmids and other kinds of vectors, in which the genetic material has been altered in a way that does not occur naturally, by means of cell or gene technology;

"import" means intentional transboundary movement of GMOs and its products thereof into Tanzania from another country;

"importer" means any person who imports or arranges for importation of a genetically modified organism replicating genetic material including sterile biological entities, viruses, viroids and plasmids;

"modern biotechnology" means the application of-

(i) in vitro nucleic acid techniques, including recombinant deoxyryibonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii) in vitro or in vivo modification of deoxyribonucleic acid (DNA) or

ribonucleic acid (RNA) so as to change any trait of an organism, or

(iii) fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are techniques used in traditional breeding and selection.

"inspector" means an environmental inspector appointed or designated as such pursuant to the provisions of the Act;

"National Biosafety Focal Point" means the Ministry responsible for environment which is designated to be

"notification in relation to GMOs" means providing information to and, where appropriate, the lodging or depositing of samples with the National Biosafety Focal Point;

"person" includes both natural and legal entities and local communities;

"placing on the market" means supplying or making available to third parties GMOs or their products;

"products" means any material derived by processing, or howsoever otherwise, from any GMOs;

"release" means any intentional introduction into the environment of a genetically modified organism or a product of a genetically modified organism and this includes release for commercial purposes, food aid, remediation, research purposes in field experiments, such as greenhouse or in aqua-culture facility, disposal of waste, import, export or transport;

"risk" means a function of the probability of harm and the severity of that harm, consequential to the transport, handling, use or disposal of a genetically modified organism;

"risk assessment" means the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic conditions and ethical values of the country or its populace which may be posed by the import, contained use, deliberate release or placing on the market of GMOs or products thereof. This includes the evaluation of secondary and long-term effects;

"socio-economic impact" means the direct or indirect effects to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, release, contained use, handling or placing on the market of GMOs or their products;

"transboundary movement" means the movement of a GMO to or from a territorial jurisdiction of Tanzania;

"transit" means where a person transports, by whatever means, a genetically modified organism into Tanzania from any other jurisdiction for the purposes conveying such genetically modified organism to any third jurisdiction;

"unintentional release" means a release that takes place without authorisation under the Act and these Regulations and takes place as a result of adventitious presence of GMOs with non-GMO shipments imported for direct use as food, feed or for processing but excludes an accident;

"use" excludes the acquisition by purchase or otherwise by a member of the general public and utilisation or dealing thereafter unless specific conditions are attached to the utilization.

PART II
GENERAL PRINCIPLES

Precautionary principle

4.-(1) Where there is a reason to believe that harm or damage may result from any undertaking involving GMOs or its products, lack of scientific evidence or certainty shall not be used as a basis for not taking preventive measures including refusing the application or imposing any condition or limitation on an approval.

(2) Approval shall not be given for the deliberate release or placing on the market of GMOs or their products which are plants and seeds for agricultural purpose until the National Biosafety Focal Point has received the results of research on the effects of the use of such GMOs or their products.

Principle of prevention

5. All approvals shall be made subject to compliance by the applicant of the principle of prevention that involves the use of special techniques such as risk assessment, or environmental impact assessment of potential effects of the planned activity followed by a decision to allow it or to prohibit it.

Strict liability

6. All approvals for introduction of GMO or their products shall be subject to a condition that the applicant is strictly liable for any damage caused to any person or entity.

PART III
ADMINISTRATION AND INSTITUTIONAL ARRANGEMENTS

Designation of the National Biosafety Focal Point

7. - (1)The Ministry responsible for environment shall be the National Biosafety Focal Point.

(2) The National Biosafety Focal Point shall on behalf of the United Republic -

(a) liaise with the Secretariat of the Cartagena Protocol on Biosafety and Biosafety Clearing House to facilitate the exchange of information among relevant bodies and authorities;
(b) co-ordinate, monitor and control the implementation, and enforcement of the provisions of these Regulations.

Functions of the National Biosafety Focal Point

8. –(1) The functions of the National Biosafety Focal Point shall include-

(a) to review and approve biosafety applications for research, confined release, pre-commercial release or placing on the market products with GMOs;
(b) to oversee the implementation of biosafety issues;
(c) to receive and forward applications to competent authorities;
(d) to collect and disseminate biosafety information to the public;
(e) to establish contacts and linkages with national, regional and international agencies and institutions;
(f) to establish database for the purpose of facilitating collection, storage, retrieval and dissemination of information relevant to biosafety;
(g) to establish and update a register of experts in biosafety;
(h) to initiate actions as may be necessary for appropriate compensation to Tanzania inhabitants or organisations who may suffer damage as a consequence of the exposure to imported genetically modified organisms or product thereof;
(i) to liase with the Secretariat of the Cartagena Protocol on Biosafety and the Biosafety Clearing – House for facilitating exchange of information among the relevant bodies and authorities;
(j) to declare through the Biosafety Clearing-House that Genetically Modified Organism or product thereof intended as food or feed for processing may be subjected to a full risk assessment;
(k) to maintain and make available to the public on request a database on Genetically Modified Organism or product thereof intended for direct use as food or feed, or for processing;
(l) to coordinate inspectors appointed or designated by the Minister and undertake inspection and other control measures to ensure compliance with these Regulations;
(m) to establish a list of genetically modified organisms and products thereof to be regulated in Tanzania and carry out its periodic review;
(n) to accept or reject an application after receiving advice from the National Biosafety Committee;
(o) to notify the applicant the results of the review; and
(p) to do all that may be deemed necessary to implement the policy and provisions of these Regulations.

(2) The Minister may by notice in the Gazette, delegate some of the functions of the Department under these Regulations to the relevant line Ministry on such conditions as may be appropriate.

Establishment of National Biosafety Committee

9. - (1) There is established a committee to be known as the National Biosafety Committee.

(2). The Committee shall be an advisory body to the National Biosafety Focal Point.

(2) The Committee shall be composed of members appointed by the Minister from government departments, agencies, non-governmental organisations and private sector whose experience shall reflect the various relevant issues of biotechnology and biosafety.

(3) The provisions of the Eighth Schedule to these Regulations shall have effect as to the composition of the Committee.

Functions of the National Biosafety Committee

10. –(1) The Committee shall advise the National Biosafety Focal Point, competent authorities or any sector Ministry on any matter which may be referred to it, and in particular, it shall-

(a) review applications submitted on different activities on or related to biosafety;
(b) advise on policies, legislation and other policy instruments relevant to biosafety;
(c) advise on the undertaking of studies and evaluation of biotechnology research for identification of concomitant risks and hazards associated with the deliberate release of genetically modified organisms in the environment;
(d) advise generally the National Biosafety Focal Point and competent authorities; and
(e) promote the participation of the private sector and the public in biosafety issues.

(2) The Committee in performing its functions shall-

(a) ensure that adequate testing of genetically modified organisms developed outside Tanzania has been undertaken in the country of origin before it is introduced in any trial programme in Tanzania;
(b) propose mitigation measures to be undertaken where an accident occurs;
(c) review regularly biosafety regulations and guidelines;
(d) advise on the undertaking of socio-economic impact assessment; and
(e) perform any other function as the National Biosafety Focal Point may, subject to the provisions of the Act and these Regulations, direct.

Ministerial Competent authority

11. - (1) There shall be designated, by the Minister responsible for environment in each Ministry dealing with issues on Genetically Modifies Organisms a competent authority to be known as the Ministerial Competent Authority .

(2) The Competent Authority shall be responsible for supervision and control of implementation of these Regulations in a Ministry and its agencies.

Functions of a competent authority

12.- (1) Subject to the provisions of these regulations the Competent Authority shall-

(a) review relevant applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market GMOs or its products thereof;
(b) review, undertake or cause to be undertaken a risk assessment of genetically modified organisms or products thereof;
(c) advise the National Biosafety Focal Point;
(d) Coordinate inspectors appointed or designated by the Minister and undertake inspection or other control measures to ensure compliance with the Act and these regulations; and;
(e) undertake assessment of socio-economic impacts as well and ethical and cultural impacts.

(2) The cost of undertaking any review of genetically modified organism or product thereof imported from outside Tanzania shall be paid by the importer.

(3) The Competent Authority shall, through the Sector Environmental Coordinator, submit a bi-annual report to the Director of Environment on supervision and control of implementation of these regulations.

Institutional Biosafety Committees

13.- (1) Institutions that are involved in any activity relating to GMOs or their products shall establish institutional biosafety committees to ensure and safety at the institutional level.

(2) The composition of the institutional biosafety committees shall be multi-disciplinary.

(3) An institutional biosafety committee shall-

(a) review the containment and confinement levels required under these regulations and guidelines for a proposed research;
(b) conduct discussions on comparative ecological, economic and social impacts of alternative approaches to attain the purpose or objectives of the proposed genetically modified organisms;
(c) institute and control safety mechanisms and approval procedures at the institutional level; and

(d) perform any other function as delegated by a relevant Ministry or competent authority.

(4) An institutional biosafety committee shall upon noticing-

(a) any significant GMO activities;
(b) significant research related research related accident or illness;
(c) problems related to GMO activities; or
(d) violation of these regulations,

report to a competent authority, appropriate authority or the National Biosafety Focal Point.

Establishment of independent body of experts

14.-(1) The National Biosafety Focal Point may appoint an independent body of experts drawn from, but not limited to, the disciplines and fields of expertise set out in sub-regulation (2) to assist it to carry out the function of risk assessment on contentious issues.

(2) The experts appointed pursuant to sub-regulation (1) as much as possible reflect the following disciplines particular regard being in each case to include ecology (in the field of community and population, ecosystem, soil and water studies), molecular genetics, population genetics, taxonomy, agronomy, virology, microbiology, marine biology, microbial physiology, pathology, entomology, atmospheric physics, human health science, veterinary science, laboratory applications and industrial processes, food safety, social sciences (such as sociology and anthropology), economics or any other relevant discipline as may be determined by the National Biosafety Focal Point.

Expertise for particular assessment

15. A person shall not be appointed as an expert in a particular assessment under subregulation (1) unless he is familiar with and have expertise in-

(a) the class or order of the host and the donor family, genus or species to be introduced; and
(b) the dynamics of the receiving environment including those environments which may be potentially affected.

Conflict of interest and alternate members

16.-(1) A person shall not sit as a member of-

(a) the Committee;
(b) an institutional biosafety committee; or
(c) any other risk assessment body,

in respect of a subject matter in which he has any direct or indirect interest of any kind.

(2) The National Biosafety Focal Point may, at the request of a panel dealing with a particular assessment or on its own initiative, nominate such other person to be member of the said panel on an *ad hoc* basis for purposes of deliberation on any matter.

Inspectorate of a Ministerial competent authority

17.- There shall be an inspectorate in each Competent Authority with responsibility to coordinate inspection and supervision.

Designation and powers of inspectors

18.- (1) The Minister in consultation with a responsible Competent Authority may designate in writing any employee of ministries or public institution either by name or office, to be an inspector for purposes of these Regulations.

(2) Inspectors shall have powers to inspect sites containing GMOs, contained facilities that may be used for research or storage of GMOs or field trial sites to ensure compliance with terms and conditions of authorization.

(3) Where an inspector in the course of inspection establishes that conditions and requirements of permit or license have not been complied with or the environment, human and animal life is at risk shall-

(a) prohibit contained use, deliberate release of a GMO into the environment or placing a product on the market;
(b) order temporary suspension of contained use, the deliberate release of GMOs into the environment or placing a product on the market;
(c) order the rectification of an identified irregularity within a time limit specified in the order; or
(d) order remedy and other measures for rectifying or reducing the consequences of adverse effect that has been caused by the GMOs or their products.

PART IV
APPROVAL OF ACTIVITY

Requirement for approval and permit by the Minister

19. There shall be no import, deliberate release, contained use, or placing on the market of the GMOs or products thereof without the prior written approval of the National Biosafety Focal Point and permit issued by the Minister responsible for environment.

Notification and approval procedure

20.-(1) Any person who intends to import, export, transport, release, use in contained condition, confined condition or place on the market the GMOs or products thereof shall submit an application in writing to the National Biosafety Focal Point approval.

(2) The application shall, in addition to the information set out in the Second Schedule, include,-

(a) general information;
(b) information relating to the GMOs or products thereof;
(c) information relating to the conditions of release, contained use or placing on the market and, where appropriate, the receiving environment;
(d) information relating to the conditions of release, contained use or placing on the market and, where appropriate, the receiving environment;
(e) information on the interaction between the GMOs or products thereof and the environment;

(f) in case of an application for contained use, an impact assessment setting out the consequences of unintentional release of the GMOs or their products;

(g) a report on the impacts and risks posed by the GMOs or products thereof to human and animal health, biological diversity and the environment in accordance with the guidelines set out in the Third Schedule to these Regulations;

(h) information on results from deliberate release in the country and other countries of the GMOs or products thereof previously or currently carried out by the applicant;

(i) information on previous approvals or rejections of the GMOs or products thereof by any other country, where approval is sought;

(j) information on where and for what purposes the GMOs or products thereof will be marketed, together with detailed instructions for use and the proposed labelling and packaging, fulfilling the requirements specified in Part C of the Second Schedule to these Regulations; and

(k) such other information as may be required by the National Biosafety Focal Point.

(3) Any person who wishes to import a GMO or its product for direct use as food or feed or for processing shall submit an application to the National Biosafety Focal Point with reference to the information on the item found in the Clearing-House of the Cartagena Protocol on Biosafety.

Applications for carrying out activities ron GMOs

21. (1) A person intending to carry out contained research on a GMO in Tanzania shall apply to the National Biosafety Focal Point for a permit in Form No. 1 set out in the Seventh Schedule to these Regulations.

(2) A person intending to carry out contained field trial on GMOs in Tanzania shall apply to the National Biosafety Focal Point for a permit in Form No. 2 set out in the Seventh Schedule..

(3) A person intending to commercially or generally release GMOs in Tanzania shall apply for a permit from the National Biosafety Focal Point in Form No. 3 set out in the Seventh Schedule..

Public awareness and participation

22.-(1) The National Biosafety Focal Point shall, upon receipt of the application under sub-regulation (2) of Regulation 20, make available the said application to the public.

(2) Subject to subregulation (1), any person may,within three months or such other period as may be specified, make comments on the application to the National Biosafety Focal Point.

(3) The National Biosafety Focal Point shall also provide for public

consultation where the public shall be informed of the consultation through the national media or the Biosafety Clearing-House and enough time shall be given for the consultation before the decision is made.

(4) The National Biosafety Focal Point shall also undertake consultations with such expert bodies as are concerned with the preservation of the natural environment, human and animal health, and representatives of the farming industry, including organic farmers.

(5) Any comment made by the public pursuant to preceding provisions of this Regulation shall be taken into account by the National Biosafety Focal Point in making its decision.

(6) The National Biosafety Focal Point shall promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of GMOs and products thereof.

Duty to disclose certain information to the public

23. The National Biosafety Focal Point shall make available to the public:

(a) information on all GMOs or their products which have been received, or 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, as specified in sub-regulation (2).

PART V
RISK ASSESSMENT

Risk assessment by applicant

24.-(1) The applicant who wishes to introduce the GMOs into the United Republic shall carry out, or cause to be carried out, an assessment of the impacts and risks posed by the GMOs or their products to human and animal health, the environment and biological diversity based upon the guidelines in the Third Schedule to these Regulations.

(2) A report in respect of the said assessment shall be prepared and submitted by the applicant to the National Biosafety Focal Point as required by Regulation 20(1)g.

Attributes of risk assessment and decision making

25.-(1) For the purpose of risk assessment and making decision on application for introduction of GMOs into the United Republic, the classification of levels of safety of GMOs and their products and the classification of Micro-organisms for determination of allowed and not-allowed

specified in the Fifth and the Sixth Schedules respectively shall apply.

(2) Without prejudice to sub-regulation (1), level of safety concern 5 shall 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.

(3) Attributes whose presence shall be treated alone or in combination as indicative of Level Safety Concern 5 are:

(a) history of adverse effects in the accessible environment or in similar environments;
(b) ability to survive and proliferate in the accessible environment;
(c) non-indigenous status in the accessible environment;
(d) high frequency of exchange of genetic information with native populations of organisms;
(e) lack of effective techniques to minimize escape of viable organisms or active products of the organism from the research site; or
(f) lack of adequate techniques to recapture or kill escaped organisms before adverse effects occur.

Socio-economic assessment

26. (1) Prior to any deliberate release of GMOs into the environment, a throrough study of-

a) their ethical and social-economic impact on the local population; concerned;
b) the traditional market and export earnings;
c) health;
d) production systems;
e) ethical, moral and social considerations;
f) the actual economic value of traditioanal species likely to be affected by introduction of the GMOs,

shall be conducted by the competent authority in collaboration with the service.

(2) Funding of the study shall be provided by the user.

Classification of safety levels

27.-(1) Biotechnology activities classified under four safety levels shall be as follows:

(a) (a) Safety level 1 – Biotechnoligical projects that are known to present no risks to the community and the environment
(b) (b) Safety level 2 – Biotechnological projects that are known to present minor risks to the community and/or the environment.
(c) (c) Safety level 3 – Biotechnolical projects that are known to present slight risks to the community and/or the environment.
(d) (d) Safety level 4 – Biotechnolical projects that are known to present risks or high risk probability for the community

and/orthe environment

(2) Any authorisation to carry out biotechnological activities shall mention the safety level (s) for which the authorisation has been granted.

(3) The provisions of the Ninth Schedule shall have effect as to the standards to be met by the laboratory intending to carry out biotechnological activities in any of the safety levels specified under sub-regulation.

Evaluation of risk assessment report

28.-(1) The National Biosafety Focal Point shall make an evaluation of the risk assessment report which shall be done on a case-by-case basis and in accordance with the guidelines set out in the Third Schedule to these Regulations.

(2) Upon completion of the evaluation of the risk assessment report, the National Biosafety Focal Point may, where it deems necessary to do so, conduct, or cause to be conducted, an assessment of risk.

(3) In evaluating the risk assessment report, the National Biosafety Focal Point and/or the panel as the case may be, shall, in addition to the guidelines, also consider and duly determine whether the import, release, contained use or placing on the market of the GMOs or products thereof will: benefit the country; and contribute to, and not undermine, sustainable development.

(4) The National Biosafety Focal Point may appoint an independent interdisciplinary panel of experts, assist in the carrying out the evaluation of the risk assessment report.

(5) The National Biosafety Focal Point and, or the panel, as the case may be, shall, upon completion of the evaluation, produce a report which shall include the following: the decision; the grounds for the decision; and the matters considered and determined by the National Biosafety Focal Point and, or the panel, as the case may be, in sub-regulation (1).

(6) The National Biosafety Focal Point may require the applicant to bear all, or any part of the costs for evaluating the risk assessment report and, or for carrying out the risk assessment.

Risk assessment parameters

29. Without prejudice to the guidelines set out in the Third Schedule to these Regulations, the risk assessment and the evaluation of the risk assessment report shall take into account, *inter alia*, the following:

(a) all relevant scientific evidence and experience;

(b) the general characteristics of both the GMO or product thereof and the parent organism(s), the vector(s) used, the genetic

modification(s) and the novel trait(s), including marker trait(s) and other sequences even when not expressed;

(c) the native environment(s) or host range of the recipient organism and donor organism(s);

(d) the intended use(s) of the GMO or product thereof, on the environment, including long-term, direct and indirect ecological impacts, particularly on centres of origin and areas with high genetic diversity of tax related to the GMO or their product.

(e) effects, long-term and direct or indirect, of the GMO or their product on human, plant and animal health;

(f) socio-economic impacts;

(g) conformity with ethical and cultural values and norms; and

(h) details of risk assessments completed elsewhere.

Risk management schemes

30. An applicant shall employ risk management schemes and procedures set out in the Fourth Schedule to these Regulations from the development of GMO through all stages of testing of the genetically modified organisms or the product thereof to its intended use or commercialisation.

Consideration of sustainable and safer alternatives

31. The National Biosafety Focal Point and, or the panel, as the case may be, shall also consider the efficacy of sustainable alternatives to the introduction of the GMOs or products thereof as well as safer alternative technologies.

PART VI
DECISION MAKING PROCEDURE

Decisions making procedure

32.-(1) The National Biosafety Focal Point shall appoint the Competent Authority to evaluate the GMOs and their products thereof.

(2) The National Biosafety Focal Point shall inform the applicant in writing of its decision that the import, export, transits, release, placing on the market, contained use or confined use, as the case may be, of the GMOs or their products thereof is:

(a) approved;

(b) approved with such conditions as it may specify; or

(c) refused.

(2) Approval shall be given where there is firm and sufficient evidence that the GMOs or their products pose no risk to human and animal health, the environment and biological diversity.

Step by step approval

33.-(1) The National Biosafety Focal Point may, in appropriate cases,

where it is satisfied that no risk is posed to human and animal health, biological diversity and the environment dispense with step-by-step introduction of GMO or their products.

(2) Without prejudice to sub-regulation (1), the National Biosafety Focal Point may direct that the activity approved shall be carried out step-by-step so that assessment of risks may be conducted at each step.

Monitoring and evaluation

34. Any approval for release or contained use shall require the applicant to carry out monitoring and evaluation of risks after the GMOs or products thereof have been imported, released, used in conditions or placed on the market.

Insurance against liability

35.-(1) The National Biosafety Focal Point shall, as a condition for approval, require the applicant to take out a policy of insurance against liability to pay compensation for damages.

(2) The applicant shall not carry out any activity in relation to GMOs or products thereof until an approval for so doing has been obtained under these Regulations.

Review of decision

36.-(1) Any approval given shall either be revoked, or subjected to conditions in addition to those originally imposed if, in the opinion of the National Biosafety Focal Point, new information or a review of existing information about the GMOs or products thereof establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle as set out in Part II .

(2) If any approval is revoked, the National Biosafety Focal Point may also, where applicable, order the destruction of any growing organisms and the sterilisation of the soil in which they are being grown, in whatever way it deems appropriate.

(3) No compensation shall be payable as a consequence of the revocation of an approval or an order for sterilisation.

Applicant to notify of new information

37. The applicant shall immediately notify the National Biosafety Focal Point where new information becomes available on the possible risks to human or animal health, biological diversity or the environment, as well as taking into account socio-economic, cultural and ethical concern after the approval has been granted.

Appeal s to the Minister

38.-(1) Any person who is aggrieved by any decision of the National Biosafety Focal Point under this Part may at any time within the period of thirty days beginning from the date on which communication of a notification of the decision was made appeal to the Minister responsible for environment..

Appeal to the Tribunal.

40. A person who is aggrieved by the decision of the Minister may within thirty days following that decision appeal to the Environmental Appeals Tribunal in such manner as may be prescribed by the Tribunal.

PART VII
RISK MANAGEMENT AND GMO TRANSPORTATION

Measures to prevent adverse effects

41.-(1) The National Biosafety Focal Point may impose such measures as may be necessary to prevent adverse effects of the GMOs or products thereof on human or animal health, biological diversity or the environment as well as taking into account socio-economic, cultural and ethical concern.

(2) In these Regulations "decision" includes any act, omission, refusal, direction, imposition of condition or order.

(3) Without affecting the generality of sub-regulation (1), measures may include the following:

(a) subject any GMOs or products thereof to undergo a period of observation commensurate with its lifecycle or generation time, at the cost of the original applicant, before it is put to its intended use, provided that this does not result in continuous trials in the field and, or in contained use;

(b) restrict or prohibit the import, release, contained use or placing on the market of any GMOs or products thereof:

(c) order the cessation of any activity that is being undertaken in violation of any of the provisions of these Regulations or any decisions made under these Regulations;

(d) order the cessation of any activity that is shown to cause risk to human or animal health, biological diversity or the environment;

(e) require the person responsible for any activity under these Regulations to take such measures as may be necessary to prevent or limit any harm or damage to human or animal health, biological diversity or the environment, or to restore the environment to its previous state as far as feasible.

(f) in the event any action as aforesaid is not undertaken by the person responsible for the activity within a reasonable time after notification, the National Biosafety Focal Point may undertake the necessary measures and all costs and expenses shall be borne by, or be recoverable from, the person responsible;

(g) in case of imminent and serious danger to human or animal health, biological diversity or the environment, and where immediate intervention is required, the National Biosafety Focal

Point shall take such measures as are necessary without prior notice, and all costs and expenses shall be borne by, or be recoverable from, the person responsible;

(h) require the applicant to submit reports periodically in respect of the monitoring and evaluation of risks carried out after the approval of the GMOs or products thereof have been imported, released, placed on the market or used in contained conditions; and

(i) prohibit the import, export, transits, release, contained use, confined use or placing on the market of the GMOs or products thereof where the National Biosafety Focal Point is satisfied that it contains characteristics or specific traits which pose risks to human or animal health, the environment, or biological diversity as well as taking into account socio-economic, cultural and ethical concern.

Unintentional release and emergency measures

42. The National Biosafety Focal Point shall ensure that, where necessary, before any release is made or contained use carried out:

(a) an emergency plan is drawn up for the protection of human and animal health, biological diversity and the environment in the event of an accident and the appropriate emergency and other services are informed of this plan in writing; and

(b) Information on safety measures and procedures to adopt in the case of an accident is supplied to persons liable to be affected by the accident. The information shall be updated and supplied periodically. It shall also be made available to the general public.

Notification of accident

43. The applicant shall inform the National Biosafety Focal Point of any accident immediately and provide the following information:

(a) the circumstances of the accident;

(b) the identity and quantity of the GMOs or products thereof released;

(c) any measures necessary to assess the effects of the accident on the environment, biological diversity and human and animal health as well as taking into account socio-economic, cultural and ethical concern; and

(d) the emergency measures taken or intended to be taken.

Identification and labelling

44.-(1) The National Biosafety Focal Point shall put in place measures to ensure that any genetically modified organism or any product of a genetically modified organism is handled, packaged and transported under conditions of safety .

(2) Any genetically modified organism or product of a genetically modified organism shall be clearly identified and labelled as such, and the identification shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability in accordance with these Regulations.

(3) Any genetically modified organism or any products containing, or consisting of, GMOs shall be clearly labelled and packaged in accordance with the Second Schedule to these Regulations and shall comply with such further requirements imposed by the National Biosafety Focal Point to indicate that it is or has been, derived from GMOs and where applicable, whether it may cause reactions, allergies or other side-effects or pose other risks.

(4) Food and feed in transits that contain GMOs shall be clearly identified and labelled in accordance with these Regulations.

Documentation and identification

45. (1) National Biosafety Focal Point shall take measures to ensure the use of an appropriate document to accompany GMOs imported, in order to give effect to the Cartagena Protocol on Biosafety, taking into account international rules and practises for the identification of GMOs.

(2) The National Biosafety Focal Point shall take measures to ensure the use of a appropriate document, including the set out in the Third Schedule (Annex V) to these Regulations that should accompany GMOs imported as food aid, and placing in the market for the direct use as food, feed and processing.

(3) The National Biosafety Focal Point shall ensure that the documentation clearly states -
(a) that the shipment contains GMOs;
(b) that whether the GMOs constituting the shipment has been approved in the country of export;
(c) that the GMOs are for aid food or placing on the market as direct use as food, feed or processing and no other use;

(d) the common, scientific, and where available, commercial names of the GMO;
(e) the transformation event code of the GMO or where available, as key to accessing information in the Biosafety Clearing-House, or its unique identifier code; and
(f) the internet address of the Biosafety Clearing-House for further information.

(4) The National Biosafety Focal Point shall in the event of non-compliance of the provisions of this Regulation take appropriate measures including the return and repatriate the GMO in question at the expense of the exporter.

Confidential business information

45.-(1) The National Biosafety Focal Point shall protect information which determines as being confidential after a claim for confidentiality is made by the applicant.

(2) In no case may the following information supplied by the applicant be kept confidential:

(a) description of the GMOs or products thereof, names and addresses of the applicant, purpose and location of the import, deliberate release (including the location and scale of the release), contained use or placing on the market of the GMOs or products thereof;

(b) methods and plans for monitoring of the GMOs of products thereof and for emergency response;

(c) the evaluation of foreseeable effects, in particular any pathogenic and, or ecologically disruptive effects;

(d) the fact that the GMOs or products thereof have been banned or subject to stringent conditions.

(3) The National Biosafety Focal Point may make available the information, notwithstanding that the information may be commercially confidential, if it decides that it is in the public interest to do so.

(4) If the applicant withdraws the application before approval, the National Biosafety Focal Point must respect the confidentiality of the information determined as being confidential.

(5) Any person carrying out any activity under these Regulations shall supply information necessary for the National Biosafety Focal Point to carry out its supervisory, monitoring or enforcement tasks or to deal with any emergency measures in relation to the activity and there shall be no claim of confidentiality in relation to such information.

Adventitious activity

46.- (1) The Competent Authority shall put in place appropriate thresholds for the adventitious presence of GMOs that are contained in non-GMO shipments imported for the purposes of aid food and placing on the market as direct use for food, feed and processing.

(2) Notwithstanding the provisions of sub-regulation (1) the Competent Authority shall endeavour to set threshold levels below a level of 0.9% for the adventitious presence of GMOs.

(3) The provisions of sub-regulations (1) and (2) shall not apply to GMOs imported where there is a high probability that such GMOs may be cultivated.

(4) An exporter shall be required to ensure and declare that there is no adventitious presence in GMOs imported other than as aid food and placing on the market for direct use as food, feed and processing as contemplated under this Regulation.

Capacity Building

47. The Competent Authority shall put in place measures to ensure the development and strengthening of human resources and institutional capacities in biosafety and biotechnology to the extent that it is required for risk assessment and risk management, for the purpose of effective implementation of the Act and these Regulations.

Export of GMOs or their products

48.-(1) Any person who intends to export GMOs or their products shall provide to the National Biosafety Focal Point a written advance informed agreement to the National Biosafety Focal Point of the importing country.

(2) The presentation of the advance informed agreement by an exporter shall in no way absolve the exporter from complying with any other laws governing foreign trade.

(3) The submission of the advance informed agreement shall not preclude the country of the exporter from taking into account other considerations before approving the export.

No export of banned GMOs or their product

49. There shall be no authorization for the import or export of GMOs or their products that are banned by the laws of the exporting or as the case may be, importing country.

Transportation of GMOs

50.(1) The users shall, in accordance with the provisions governing the transportation of GMOs, take sufficient measures to-

(a) prevent the escape of GMOs, given such possibilities as accidents on the way so that they are not crossed with domesticated indigenous populations;
(b) be sure that they are well identified and that they reach their destination as intended;
(c) ensure that the process is supervised by a competent authority with experience in the management related problems.

(2) No cage or container shall be used for transportation unless it is approved by the competent authority.

(3) An exporter or importer shall contact the National Biosafety Focal Point for directives related to the purchase of a cage approved by airline companies for the transport GMOs.

Measures to be taken during transportation

51. A person transporting GMOs shall during the transportation take the the following measures-

(a) GMOs are put in an unbreakable locking container clearlyblabelled

and sealed in order to avoid leakages;

(b) the locking container is put in another container clearly labelled and properly sealed for transportation;

(c) the transport equipmrnt is decontained by autoclave after the transported GMOs are transferred into new container;

(d) accounting procedure is set up to ensure that the number of containers exported are the same upon delivery.

Transportation within institutions

52.(1) Any GMOs to be transported within and between institutions, shall first be put in a primary container and placed in unbreakable secondary container.

(2) The container shall contain a lebel bearing the address of the sender to be contacted in case of loss or damage of the parcel.

(3) The parcels shall contain labels indicating the quantity transported.

Transportation of micro-organism

53. Micro-organism shall be transported in accordance with international norms in force and shall not, for any reason, be transported in personal luggage by public or private transport.

GMO in transit

54. A person or company transporting GMOs through the national territory in transit to other countries shall inform the National Biosafety Focal Point in advance, and comply with the national requirements relating to containment and transport, as set out from time to time.

GMO food and feed aid or food assistance

55.-(1) Genetically modified food and feed assistance introduced into the United Republic shall comply with the prior informed consent principle and the notification requirement in accordance with Article 8 of the Cartagena Protocol on Biosafety, 2000.

(2) Food and feed consignment involving grain that contain GMOs shall be milled prior to distribution to the beneficiaries.

PART VIII
LIABILITY AND REDRESS

Strict liability

56.-(1) Any person or his agent who imports, transits, makes contained or confined use of, releases, carries out any activity in relation to GMOs or products thereof or places on the market a GMO shall be strictly liable for any harm, injury or loss caused directly or indirectly by such GMOs or their products or any activity in relation to GMOs.

(2) The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity as well as taking into account socio-economic, cultural and ethical concern.

(3) Liability shall be attached 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 GMOs or their products .

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

Liability of officer of corporation

57.-(1) Where liability under Regulation (29) is incurred by a body corporate, any director, manager, secretary or similar officer of the body corporate shall be similarly liable unless he can show that he did everything in his power to prevent the import, deliberate release, placing on the market or contained use which caused the damage in question.

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

(3) 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 can prove that one or more of the persons so proceeded against could have caused the damage.

Extent of liability for environmental damage

58. 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 National Biosafety Focal Point.

Liability for socio-economic harm or damage

59. Liability shall also extend to harm or damage caused directly or indirectly by the GMOs or products thereof to the economy, social or cultural principles, 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 areas or community.

Indemnity

60.-(1) An applicant shall indemnify:

(a) any other person who deliberately release or markets GMO(s) or products thereof; and

(b) any person who manufactures, processes or markets food, food ingredients or animal feed containing or derived from GMOs against any civil liability where the GMOs or products thereof in question was first imported, deliberately released, used in contained conditions, or placed on the market by the applicant.

(2) An applicant shall indemnify against any civil liability any person who fails to label seeds, food, a food ingredient or animal feed containing or derived from GMOs, but where the applicant can show that he took all reasonable steps to prevent such failure the indemnity shall no apply.

Limitation period

61.-(1) The right to bring any action to redress the harm caused by the GMOs or products thereof shall lapse only after 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 co-relate the harm with the GMOs or products thereof, having regard to the situation or circumstance of the person or community affected.

Right of individual and legal persons to sue

62.-(1) 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 these Regulations, including any provision relating to damage to the environment and biological diversity:

(a) in that person's or group of person's interest;

(b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;

(c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;

(d) in the public interest; and

(e) in the interest of protecting environment or biological diversity.

(2) 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.

Consent of National Biosafety Focal Point no defence

63. It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the National Biosafety Focal Point.

Protection for reasonable disclosure

64.-(1) 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 was disclosing evidence of any risks posed by GMO(s) or products thereof to human or animal health, the environment or biological diversity as well as taking into account socio-economic, cultural and ethical concern in accordance with sub-regulation (2).

(2) Sub-regulation (1) of this Regulation applies only if the person

concerned

(a) disclosed the information to:

(i) any authority which has the jurisdiction over matters pertaining to the protection of human or animal health, the environment or biological diversity as well as taking into account socio-economic, cultural and ethical concern;

(ii) any authority having powers of prosecution or enforcement; or

(iii)Parliament including its committees;

(b) disclosed the information concerned to one or more news media and on clear and convincing grounds believed at the time of the disclosure:

(i) that the disclosure 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

(c) disclosed information which, before the time of the disclosure of the information, had become available to the public, whether in the country or elsewhere.

(3) Sub-regulation (1), 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.

Inducement and threat

65.-(1) No person shall induce any other person to exercise or refrain from exercising his right as aforesaid by giving or promising any advantage.

(2) No person shall threaten to take any action against any other person for exercising or intending to exercise any right in relation to any matter provided for under these Regulations.

PART IX
OFFENCES AND PENALTIES

Offences and penalties

66.-(1) Any person who-

(a) imports, exports, transits, releases, places on the market or makes confined use, contained use of any GMOs or products thereof without the written approval of the National Biosafety

Focal Point;

(b) violates any conditions attached to the grant of approval under these Regulations;

(c) fails to furnish any information as required by the provision of these Regulations;

(d) provides false, misleading or deceptive information in order to secure an approval;

(e) does not label, package or identify any GMOs or products thereof in a manner that is false, misleading or deceptive or in contravention of any regulation made under these Regulations;

(f) labels, packages or identifies any GMOs or products thereof in a manner that is false, misleading or deceptive in contravention of any regulation made under these Regulations;

(g) exports GMOs or products thereof without the advanced informed agreement of the importing country;

(h) participates in any proceedings in respect of a subject matter to which he has any direct or indirect interest of any kind;

(i) fails to have a valid policy of insurance against liability to pay compensation for damage; or

(j) violates any other provision of these Regulations or any condition or requirement imposed under these Regulations;

commits an offence and is liable on conviction to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years or to both.

(2) Any person shall, upon conviction of an offence under sub-regulation (1) (a), (b) or (d), be prohibited from engaging in any activity in relation to GMOs or their products which prohibition shall extend to any corporation, body or legal entity which may be used to avoid the effect of the said order.

(3) Any person who repeatedly commits an offence other than offence referred under sub-regulation (1):

(a) where the offence is committed by an individual person, the court may prohibit that person from engaging in any activity relating to GMOs or their products; or

(b) where the offence is committed by a corporation and the court feels that a custodial sentence be imposed then the executive officer in charge of such corporation at the time during which the offence is committed shall be liable for a penalty.

Loss assessed upon conviction

67. Whenever any person is convicted of an offence under these Regulations and it appears that such person has by that offence caused loss or damage, including the cost incurred or likely to be incurred by any organ of state in rehabilitating the environment or preventing damage to the environment, the court may in the same proceedings at the written request of

the Minister or other organ of state and in the presence of the convicted person, ascertain the amount of the loss or damage so caused.

Enforceability of judgment

68.-(1) The decision of the court and such order issued in respect of the decision shall have the same force and effect and be executable in the same manner as if it had been given in a civil action dully instituted before a competent court.

(2) Without prejudice to sub-regulation (1), the court may also summarily enquire into and assess the monetary value of any advantage gained or likely to be gained by such person in consequence of that offence, and, in addition to any other punishment imposed in respect of that offence, the court may order the award of damages, compensation or a fine equal to the amount so assessed.

(3) The court may, upon application by any person who is interested on the subject matter of the case order such person to pay the reasonable costs incurred by the public prosecutor and the organ of state concerned in the investigation and prosecution of the offence.

Liability of employer

69. Whenever any manager, agent to employee does or omits to do an act which it had been his task to do or to refrain from doing on behalf of the employer and which would be offence under these Regulations for the employer to do or omit to do, and the act or omission of the manager, agent or employee occurred because the employer failed to take all reasonable steps to prevent the act or omission in question, the employer shall be guilty of the said offence and liable on conviction to the penalty to a fine of not exceeding five million shillings or to imprisonment for a term of five years or to both.

Liability of manager, etc.

70. Whenever any manager, agent or employee does or omits to do an act which it had been his task to do or to refrain from doing on behalf of the employer and which would be an offence under these Regulations for the employer to do or omit to do, he shall be liable for offence in respect of the omission or refrain from doing as if he were the employer.

Community right for GMO free zones

71. – (1) The Minister responsible for environment shall take measures for the creation of geographical areas and declare them being GMO free zones where release of any GMO is prohibited taking into account the provisions of Article 26 of the Cartagena Protocol on Biosafety and the provisions of the Convention on Biological Diversity on the conservation and sustainable utilization of biological diversity.

(2) The National Biosafety Focal Point shall develop policies that protect the right of communities to declare GMO free zones.

PART X
GENERAL PROVISIONS

Insurance

72. – (1) An applicant for a permit or licence under regulations shall satisfy the National Biosafety Focal Point that he has subscribed to an insurance policy covering the risks likely to arise out of the activity for which the permit or licence is required.

(2) An applicant shall, upon written instructions by the National Biosafety Focal Point, subscribe to an insurance policy to cover risks caused by that GMO or GMO products thereof.

Environmental Impact Assessment

73. – (1) An application for field trial or release of GMO shall not be permitted or licenced under these Regulations unless an environmental impact assessment under these Regulations has been carried out in accordance with the Act and the Environmental Impact Assessment and Audit Regulations, 2005.

(2) An operator of a GMO facility shall carry out an annual audit of the environmental performance of the site or plant and shall submit a report to the National Environment Management Council and the National Biosafety Focal point.

Reporting procedures

74. – (1) A person licensed to carry out any activity under these regulations shall submit bi-annual reports on the conduct of the licenced activity to the Director of Environment.

(2) Where special reporting procedures are made the condition of a licence granted under these Regulations, those procedures shall take precedence over the submission of bi-annual reports under sub-regulation (1).

Duty to keep records

75. The holder of a licence under these Regulations shall-

(a) keep a record of the licensed activity and all transactions related to it; and

(b) submit the record referred to in paragraph (a) to the National Biosafety Focal Point every six months from the commencement of the licenced activity

Register of permits or licences

76. The National Biosafety Focal Point shall maintain a register of all permits or licences issued under these Regulations for purposes of transparency and accountability.

Cancellation of permit or licence

77. The Minister responsible for environment may suspend or revoke a permit or licence issued under these Regulations where he is satisfied that –

(a) the conditions of the grant of the licence have not been complied with;

or

(b) the continued operation of the activity is or is likely to be injurious to the health of the neighbouring community or to the environment in general.

Fees

78. The fees prescribed by the Minister in the Environmental Management (Fees and Charges) Regulations, 2008 shall be paid for the various applications and licences under these Regulations.

Operation of Regulations

79. These Regulations shall, without prejudice, operate in addition to any other Regulations or standards made under any written law.

Guidelines or manuals

80. (1) The Minister may from time to time issue guidelines, manuals or orders to facilitate effective implementation of these Regulations.

(2) Without prejudice to sub-regulation (1) the guidelines and manuals may be on-

(a) procedure for handling request and inspections of GMOs
(b) Risk Assessment and Risk Management
(c) confined field trials;
(d) contained trials; and
(e) on any other aspect on and relating to GMOs.

Amendment of Schedules

81. The Minister may amend Schedules to these Regulations.

Transitional provisions

82.-(1) After the date of the entry into force of these Regulations, any person carrying out any activity in relation to GMOs or products thereof shall submit an application for approval for the said activity in accordance with the provisions of these Regulations.

(2) The application shall be submitted to the National Biosafety Focal Point within a time limit to be determined by the National Biosafety Focal Point.

(3) If the application has been made within the prescribed time limit, the activity in respect of which the application is made may continue until a decision is made by the National Biosafety Focal Point under these Regulations.

(4) Any application pending at the date of entry into force of these Regulation shall be subject to the provisions of these Regulations.

FIRST SCHEDULE

(Made under Regulation 20 (2))

APPLICATION FOR INTRODUCTION OR RELEASE OF GMOs INTO TANZANIA

General information requirements

1.-(1) Any person who wishes to introduce GMOs into the United Republic shall be required to make application to the National Biosafety Focal Point.

(2) Application shall be made in Form GMO-1 specified under this schedule.

(3) Without prejudice to sub-paragraph (2), the applicant shall be required to provide the following informations:

(a) name and address;

(b) qualification regard any specific expertise on matters relating to GMOs; and

(c) information regarding qualification of persons to be involved in implementation of the project, including those who shall be responsible for supervision, monitoring and safety.

Further information

2. Without prejudice to generality of regulation (3), the applicant shall be required to provide further information on:

(a) 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 been authorized by an agency with the mandate to do so; and

(b) human effect on health and biological diversity of our country taking into account social economic, cultural and ethical concerns.

Specific information requirements

3. In additional to the general information requirements a person who wishes to introduce GMOs into the United Republic shall be required to provide specific information in relation to matters specified in items I, II, III and IV.

I. 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, cultivars 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

(6) 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 n 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

(7) 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

II: 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 sued 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 genetically modified organisms 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 pat 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 biota
(3) Proximity to significant biotopes 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 faffected
(8) Geographical, geological and pedological charactersits
(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.

III: Information Relating to the Interactions Between the GMO(s) or their Products 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 or 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 impact

(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

IV: Information on Monitoring, Control, Waster 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

SECOND SCHEDULE

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF PLACING GMOs ON THE MARKET

(Made under Regulations 20(2) (j) and 42 (3))

Any person who wishes to notify for placing on the market product shall provide the following information in addition:

I. ***The following information shall be provided in the notification for placing on the market products, in addition to that of Third Schedule:***

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.

II. ***The following additional information shall 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 Item 1, 2, 3, and Item II 1 and 2.

III. ***The following information concerning labeling of products thereof shall 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… (specify 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 Item III 1 or .2, the words "This product contains genetic material (nucleic acids) from GMO(s)" or "This product is based on raw materials from GMO(s)"

THIRD SCHEDULE

(Made under Regulations 20(2)(g), 24, 26,27 and 43)

RISK ASSESSMENT PARAMETERS

1. The applicant shall carry out an assessment prior to the use or release of genetically modified organisms or products thereof as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies,.

2. The assessment shall take the following parameters into consideration including any other parameter deemed to be relevant:

I. 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.

II. 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.

III. 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 extrachromosomal;
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. Propability 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. Allogenicities, 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;

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

(A) 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 nay;
6. Impacts on human and animal health and the environment;
7. Impaction Socio-economic cultural and ethical concern;
8. Measures for counteracting adverse impacts;
9. Length of time the organism has been in sue;
10. Genetic stability;
11. Likelihood of gene transfer to other organisms;

12. Fossil and living nearest relative species;
13. Biological and biochemical differences form related living species; and
14. Information on previous uses since resuscitation.

(B) 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; and
10. Living species related to the species from which the gene was taken

V. 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; and
   (i) availability of appropriate therapies.

VI. 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 genetically modified organisms;
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 Social-economic, cultural and environment.

VII. Socio-economic considerations

In parallel to and simultaneous with the scientific risk assessment, an evaluation of the socio-economic risks shall be undertaken 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 genetically modified organisms 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.

FOURTH SCHEDULE

(Made under Regulation 29)

RISK MANAGEMENT SCHEMES

The applicant shall 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:

I. Imported products of genetically modified organisms 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.

II. Imported microbial genetically modified organisms for human and animal health;

Besides the limited observation specified in 1, experiments shall 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.

III. Imported genetically modified organisms for contained use:

(a) The products of genetically modified organisms 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.

IV. Products of genetically modified organism made locally:

(a) Trial on experimental animals will be made when the product of the genetically modified organisms 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.

V. Genetically modified organisms 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 genetically modified organisms has been made;

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

VI. Imported plant or microbial genetically modified organism for release:

(a) The reports from releases in areas other than the state of import shall be thoroughly evaluated by the National Biosafety Committee. Particular emphasis shall 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 shall 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.

VII. Imported animal genetically modified organism for release:

(a) The reports from releases in areas other than the state of import shall be thoroughly evaluated by the National Biosafety committee. Particular emphasis shall 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.

VIII. Plant or microbial genetically modified organisms produced locally for eventual release;
(a) Laboratory biomolecular 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 shall 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 shall be destroyed;
(f) The product form the genetically modified organism shall be subjected to the procedure in IV;
(g) The monitoring of the spread and behaviour of any released plant or micro-organism genetically modified organism shall 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 genetically modified organisms or its successor shall provide annual reports to the competent authority.

IX. Animal genetically modified organism 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 shall 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 shall 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 IV;
(g) The monitoring of the spread and behaviour of any released animal genetically modified organism will continue for at least 30 years.

X. General Requirements:

(a) All trials, experiments or observations specified in all the above cases (I-IX) are put in their logical sequence and shall 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 genetically modified organisms or products thereof shall 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 genetically modified organisms or products thereof shall be subject to approval by the National Biosafety Committee. All final approval for the use of genetically modified organisms or products thereof shall 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 shall notify its decision in writing to the competent authority; and

(d) Whenever there is a need to dispose of genetically modified organism or the product thereof upon the completion of experiment or trial shall submit reports to the National Biosafety Committee for evaluation and necessary compliance orders.

FIFTH SCHEDULE

(Made under Regulation 25(1))

CLASSIFICATION OF MICRO-ORGANISMS 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

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

Moderate-Risk Oncogenic Viruses

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

3. Class 5 Agents

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

Foot-and-mouth disease virus

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

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.

SIXTH SCHEDULE

(Made under Regulation 25(1))

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.

SEVENTH SCHEDULE

FORMS FOR GMOs ACTIVITIES

(Made under Regulation 21)

Form No. 1: Application Form for Contained GM Research in Tanzania (Regulation 21(1))

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

Γ **CBI COPY**
Γ
CBIDELETED
Γ **NO CBI**

Instructions

This application form consists of seven parts which must be completed for any type of research involving **genetically modification** under containment in Tanzania.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application for use by the Tanzanian regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

Please conduct a public notification in accordance Biosafety regulations of Tanzania

The appropriate fee as stipulated in the Biosafety regulations must accompany the application. Please note that the Vice president's office does not accept cash.

Applications must be received by National Biosafety Focal Pont (NBFP) at the address shown below at least 180 days in advance of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380, Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

Part 1: Administrative Information

Applicant:
[Name of applying institution, including the name of the Principal Investigator or other key personnel.]

Name of Institution:
Address:
P.O. Box:
Physical Address:
Street:
District:
Town/City
Telephone (s):
Fax:
E-mail:

Contact Details of Principal Investigator/Lead Scientist:

Name of Lead Scientist:
Address:
Telephone (s):
Fax:
E-mail:

Purpose of Application:
[Application for contained GM research (name of crop/animal species and introduced trait).]

Previous Applications or Approvals:

Proposed Duration:

Expected starting date:

Expected termination date:

Part 2: Information about the Project

2.A Title of the project

2.B Proposed date of commencement of the project

2.C Proposed date of completion of the project

2.D Brief description of the project

Part 3: Description of the GMO

3.A Common and scientific names of the parent organism

3.B Vector(s) or methods to be used for the transfer of genetic material

Indicate method of transformation; promoter, selection marker to be used

3.C Class of the modified trait

3.D Identity and function of the gene(s) responsible for the modified trait

3.E Organism from which the gene(s) responsible for the modified trait(s) were isolated

3.F Organisms or tissues to be used in association with the GMO

Table 1: Summary information of GMO

3.A		3.B	3.C	3.D and 3.E	3.F
Common name of parent organism	**Scientific name of parent organism**	**Vector(s) or method of transfer**	**Modified trait**	**Identity and function of gene(s) and organism of origin**	**Organisms or tissues to be used with the GMO(s)**

Part 4: Additional information for a GMO that is a whole plant or is to be used in conjunction with a whole plant

4.A Weediness of the parent organism

4.B Stage of plant development to be grown

4.C Growing medium for the plants

Part 5: Risk assessment and management

Health and safety of people

5.A Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (*i.e.* the risk) from the proposed genetic modification(s)

5.B Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (*i.e.* the risk) from an unintentional release of the GMO(s) into the environment?

5.C Kinds and level of notifiable risk dealing

5.D Transportation of the GMO(s) outside the contained facility

Indicate if the transformed materials will be transported outside the contained facility, and if so how

5.E Disposal of the GMO

Describe how the transformed materials will be disposed

5.F Other actions and precautions to be taken to minimise risks posed by the proposed dealing(s)

Describe other safety measures will be put in place to minimize any potential risks

Part 6. Description of the containment facility

Information of the facilities to be used

Give brief description of the containment facility and provide sketch

Facility type:

Physical containment level:

Address:

Facility contact person details

Name:

Business phone number:

Mobile phone number:

Facsimile number:

E-mail address:

Part 7: Declaration and Signatures

I hereby declare and certify that the information in this application is complete and accurate to the best of my knowledge and belief.

Principal Investigator of the Applying Institution

Name:

Signature**:** Date:

Project Supervisor

Name:

Signature Date:

Form No. 2. Application Form for a Confined Field Trial (Regulation 21(2))

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

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Instructions

This application form consists of seven parts which must be completed for **each individual genetically modified plant species** proposed for environmental release in a confined field trial in Tanzania.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application with confidential information for use by the Tanzanian regulatory bodies.

Please provide 5 copies of the application for use by the Tanzanian regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

The appropriate fee as stipulated in the Biosafety regulations must accompany the application. Please note that the Vice president's office does not accept cash.

Applications must be received by National Biosafety Focal Pont (NBFP) at the address shown below at least 180 days in advance of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380, Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

1. Administrative Information

Applicant:
[Name of applying institution, which may also include the name of the Principal Investigator or other key personnel.]

Name of Institution:
Address:
P.O. Box:
Physical Address:
Street:
District
Town/City
Telephone (s):
Fax:
E-mail:

Contact Details of Principal Investigator/Lead Scientist:
Name of Lead Scientist:
Address:
Telephone (s):
Fax:
E-mail:

Purpose of Application:
[Application for a confined field trial for (name of crop species and introduced trait).]

Previous Applications or Approvals:
[Information on the status of this crop and trait, including pending, approved, or denied applications for field trials and commercial releases here or in other jurisdictions. Indicate also if this is a new application or a renewal.]

Proposed Location and Size of Trial:
[Name, address, email, phone, and facsimile of the Trial Manager as well as GPS information or description of the exact location and size of the trial site (attach sketch map).]

Proposed Duration of Trial:

Expected starting date:

Expected termination date:

2. Plant Information

2.1 Unmodified Plant Information

This section describes the characteristics of the unmodified plant as it relates to confinement. Important information pertains to the plant's reproductive mechanisms and its ability to escape, establish, and persist in the environment into which it is being introduced.

Plant Species Name (common and scientific):

Centre of Origin:

[What is the centre of origin of the unmodified plant?]

Reproductive Mechanism of the Plant:
[Describe the reproductive biology of the plant. This information may be obtained from Organization for Economic Co-Operation and Development (OECD) biology consensus documents or similar sources, and should include relevant information on: inter- and intra-specific breeding; pollen production, dispersal, and viability; seed production and dispersal; seed dormancy; capacity for vegetative reproduction.]

Tendency to Weediness:
[Is the unmodified plant regarded by agricultural experts as a weed in Tanzania or elsewhere? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plant? NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.]

Toxicity and Allergenicity:
[Is the plant species known to be a source of substances that are toxic or allergenic to humans or animals? If yes, identify the substances and levels that induce toxicity or allergenicity and the affected species.]

Allelopathy:
[Is the plant species known to be allelopathic? If yes, give details]

2.2 Modified Plant Information

This section is intended to provide information on known or intended effects of the genetic modification or introduced trait that may effect confinement measures employed in the confined trial.

Describe the Intended Phenotypic Changes to the Plant:

Intended Reproductive Effects:
[Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes effect strategies for confinement?]

What is the source of the genetic material? Is the source of the genetic material likely to affect the safe conduct of a confined field trial? If yes, how?
[Describe any known or intended introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.]

Changes in Toxicity or Plant Composition:
[Describe any changes to toxicity, allergenicity, or significant changes in composition intended by the genetic modification.]

Describe the Features of the Genetic Construct:
[Include coding sequences, promoters, enhancers, termination, and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex.]

Stable Integration of the Inserted DNA:
Indicate the site of Integration of the Introduced DNA

Indicate how stable integration of the DNA was demonstrated

Expression Products of the Introduced Gene(s):
Provide information for each protein product of the introduced gene(s) - maximum level of expression in the edible portions of the plant, whether the protein known to be allergen or toxic to humans or animals

3. Trial Description

This section describes the purpose of the field trial, anticipated planting and harvesting dates, the experimental design and data to be collected, including anticipated use of pesticides, fertilizers and any agro-chemicals. Include a description of the habitat at the site, and any organisms of conservation concern that may be in the general area.

Trial Description:

4. Genetic Confinement

This section describes the measures to be taken to ensure confinement of the genetically modified plants and genes. It is based on knowledge of the unmodified crop and the intended genetic modification.

Provide a map showing the location of the trial site, surrounding fields, and relevant geographic features such as streams or waterways.

Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting in viable seeds?

Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site:
[Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology.]

Describe measures in place to control trial plant volunteers after termination of the trial:
[Describe the crops to be allowed following the confined trial, duration of monitoring for volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site.]

5. Material Confinement

This section describes the mechanisms by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

Packaging:

[Describe how the genetically modified plant material will be packaged and labelled for transport to the trial site and measures for cleaning and/or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported.]

Harvesting, Transport, and Storage:
[Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported.]

Disposal and Clean-Up:
[Describe how surplus planting material will be disposed of at the trial site, how any equipment used during planting or other farm operations will be cleaned, and how harvested materials and crop residues will be disposed.]

Site Security:
[Describe measures in place to ensure security of the trial site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc…]

6. Records, Personnel, and Planning

Records and Documentation:
[Describe measures in place to ensure adequate documentation of all confinement measures and data requirements as described herein.]

Contact Details of Site Manager:

Name of Site Manager:

Address:

Telephone (s):

Fax:

E-mail:

Personnel:
[Briefly describe competence of the Site Manager and measures in place to ensure that trial personnel will have appropriate education, experience, and training to adequately perform assigned duties for confinement and technical requirements of the trial.]

Contingency Plans:
[Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the Authorized Party, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects.]

Part 7: Declaration and Signatures

I hereby declare and certify that the information in this application is complete and accurate to the best of my knowledge and belief.

Principal Investigator of the Applying Institution

Name:

Signature**:** Date:

Project Supervisor

Name:

Signature Date:

Form No. 3. Application Form for a Commercial/General Release of GMOs in Tanzania (Regulation 21 (3))

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

Γ **CBI COPY**
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CBIDELETED
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Instructions

This application form consists of seven parts which must be completed for each individual genetically modified plant species proposed for environmental release in a confined field trial in Tanzania.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application for use by the Tanzanian regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

Please provide an electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below.

Please conduct a public notification in accordance Biosafety regulations of Tanzania.

The appropriate fee as stipulated in the Biosafety regulations must accompany the application. Please note that the Vice president's office does not accept cash

Applications must be received by National Biosafety Focal Pont (NBFP) at the address shown below at least 180 days in advance of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380, Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

PART I

1. BRIEF DESCRIPTION OF THE GENETRICALLY MODIFIED PLANT

Include specific and common names of the plant, the country of origin of the plant and a description of the genetically modified trait.

2. GENERAL RELEASE

Detail specific instructions for the storage and handling of the plant, or viable plant parts.

When will general release be implemented?

Where will general release take place?

Detail the type of environment and the geographical areas for which the plant suited.

Who will undertake the general release?

Estimate the amount of production of the genetically modified plant within Tanzania per annum, or the amount of viable plant product to be imported into Tanzania per annum.

3. DESCRIPTION OF ANY PRODUCT DERIVED FROM THE PLANT

Identify the part of the plant to be used for the product, the type of product, and the use of the product, the market sector in which the product will be marketed and the trade name of the product.

Specify the exact conditions of use of the product.

Provide information on the proposed labeling of the product for marketing.

State whether the benefits of the product are available in any other non-genetically modified form. If so, state why the genetically modified form should be approved for general release when other, non-modified products are available.

Details specific instructions for the storage and handling of viable plant products that will avoid misuse or escape of the genetically modified plant into an environment for which it was not intended.

Detail the likelihood of the genetically modified plant or its products being exported from Tanzania, particularly if such export could result in the introduction of the plant into its centre of origin.

4. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

Submit a list of previously authorized activities with the GMO in

(a) Tanzania
(b) East Africa
(c) Other countries

Include information on the country, year, location and the authority from which permission was obtained to run the field trials.

Provide full data on the field performance of the genetically modified plant, including the efficacy of the introduced trait.

5. POLLEN SPREAD

Identify all methods of pollination applicable to the plant.

Identify pollinating agents and the distances to which pollen is known to spread.

Identify any plants in the area of general release that may become cross-pollinated with the genetically modified pollen.

Describe methods to be used to prevent the spread of genetically modified pollen to wild type plants.

6. SEED DISPERSAL

If seed to be sold, state whether the seed is hybrid.

Describe methods to be used to limit the dispersal of genetically modified seed into the environment.

If seed dispersal will occur describe what volumes of seed are likely to be dispersed, how this seed will interact in the environment and what long term effects the seed is likely to have on the environment.

7. VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS

Describe methods of vegetative reproduction that are available to the plant.

Describe methods to be used to limit vegetative spread of the genetically modified plant into the environment.

8. FOREIGN GENES AND GENE PRODUCTS

Identify all foreign genes in the genetically modified plant.

Describe the gene products that are derived from the foreign genes.

Describe the biological activity associated with the foreign gene products.

Provide information on the rate and level of expression of the foreign genes and the sensitivity of the measurement of the rate and level. State whether expression is constitutive or inducible. Are foreign genes expressed throughout the plant or only in certain organs or tissues?

Provide protocols for the detection of the foreign genes in the environment including sensitivity, reliability and specificity of the techniques.

9. RESISTANCE

Detail whether the genetically engineered plant is able to initiate resistance, in any biotic component of the environment, to any biologically active foreign gene product.

Detail what methods are available to minimize the risk of resistance developing in the environment.

Detail how resistance will be managed during general release of the genetically modified plant.

10. HUMAN AND ANIMAL HEALTH

Please take cognizance of the requirements pertaining for food and feed safety, as contained in the guidelines for use of GMO's. You are required to follow these guidelines in compiling the information for your application.

State whether the genetically modified plant or its products will enter human or animal food chains.

Detail the results of experiments undertaken to determine the toxicity of the foreign gene products (including marker genes) to humans and animals.

If the foreign gene products are toxic or allergic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.

What are the implications of the proposed activity with regard to the health and safety of the workers, cleaning personnel and any other person that will be directly or indirectly involved in the activity? Please take into consideration the provisions of the Occupational Health Safety Act, Cap. 297 accompanied regulations.

Further to the question raised above, indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity.

11. ENVIRONMENTAL IMPACT AND PROTECTION

Detail any long-term effect the general release of the genetically modified plant is likely to have on the biotic and abiotic components of the environment.

Provide data and information on ecosystems that could be affected by use of the plant or its products.

Specify what effect the general release of the genetically modified plant will have on biodiversity.

Specify the measures to be taken in the event of the plant or product being misused or escaping into an environment for which it is not intended.

If the foreign genes give rise to crops resistant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

12. SOCIO-ECONOMIC IMPACTS

Specify what, if any, positive or negative socio-economic impacts the genetically modified plant will have on communities in the proposed region of release.

13. MONITORING AND ACCIDENTS

Indicate the methods and plans for monitoring of the GMO

Indicate any emergency procedures that will be applied in the event of an accident.

14. PATHOGENIC AND ECOLOGICAL IMPACTS

Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts.

15. WASTE DISPOSAL

Where only a portion of the genetically modified plant will be used for the product, how will the unused plant parts be disposed of?

16. RISK MANAGEMENT

Please indicate any risk management measures that would be required during the trial.

17. COMPLETE THE AFFIDAVIT.

The affidavit is an inseparable part of the application form.

AFFIDAVIT/STATEMENT

(To be completed in the presence of a Commissioner of Oaths)

ID Number……Age……

Residing address……..

Working address……

Tel……(w)……..(h)……..(Cell)

Declare under oath in English/confirm in English

……

……

I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Place:……. Date:……..

Time:……..

Signature:…….

I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponent's signature/mark/thumb print was placed thereon in my presence.

At:…….on……at…….

Commissioner of Oaths

(Details to be provided on physical and postal address e.g. stamp of police station)

……

Force number/Rank/Name - print

EIGHT SCHEDULE

(Made under Regulation 9(3))

COMPOSITION, MEETING AND PROCEDURE OF THE NATIONAL BIOSAFETY COMMITTEE

1. The National Biosafety Committee shall consist of:

a. The Director of Environment who shall be the Chairman;
b. A representative of the Vice President's Office;
c. A representative of the Ministry of Livestock and Fisheries ;
d. A representative of the Ministry of Communication, Science and Technology;
e. A representative of the Ministry of Industry and Trade;
f. A representative of the Ministry of Water and Irrigation;
g. A representative of the University of Dar es Salaam;
h. Two representatives of the Sokoine University of Agriculture;
i. A representative of the Commission of Science and Technology ;
j. A representative of the National Institute of Medical Research;
k. A representative of the Tanzania Food Nutrition Centre;
l. A representative of the National Environment Management Council; and
m. A representative of the Tanzania Chamber of Commerce, Industry and Agriculture.

2. At its first meeting members of the Committee shall elect amongst their number a Vice Chairman.

3. Members of the Committee, other than those appointed by virtue of their offices, shall hold office for three years and, unless their membership is otherwise terminated due to misconduct or non attendance without excuse three successive meetings of the Committee, shall be eligible to reappointment for one further term.

4. The National Biosafety Committee shall meet at times and places as the Chairman may, after consultation with the Secretary, determine.

5. An ordinary meeting of the Committee shall be convened by the Chairman and the notice specifying the place, date, and time of, and agenda for, the meeting shall be sent to each member at his usual place of business or residence not less than fourteen days before the date of the meeting.

6. The Chairman, or in his absence the Vice-Chairman, shall convene a special meeting of the Committee in writing signed by not less than three members of the Committee and, where such special meeting in convened, the agenda for such meeting shall be circulated to each member at his usual place of business or residence at least not less than three days before the date of the meeting.

7. A meeting of the committee shall be presided over by the Chairman or in his absence, by the Vice-Chairman and when both the Chairman and the Vice-Chairman are absent, by a member elected by those members present at that meeting.

8. The quorum at any meeting of the Committee shall be half of the members.

9. The Committee may establish such sub-Committees as it sees fit to enable it to discharge its functions.

10. The Committee and any Sub-Committees established by the Committee shall have the power to co-opt any person on to the committee or sub-Committee either generally or for a specific item of business and such co-opted person shall have all the rights and duties of a member of the Committee or sub-Committee except that such co-opted person shall not have any right to vote on any matter before the Committee or Sub-Committee.

11. A member who has any interest, direct or indirect in any matter coming before the Committee or sub-Committee shall, as soon as is reasonably practicable, disclose the nature of that interest to the Chairman or Vice-chairman and shall not, thereafter take part in any decision on that matter nor, except with the consent of a majority of the members present at that meeting, take part in any deliberations of that meeting.

12. Subject to the provisions of this Schedule, the Committee shall regulate its own proceedings.

15. The Committee shall prepare an annual report setting out its current activities and indicating its future activities.

Dar es Salaam,
……., 2009

BATILDA S. BURIAN
Minister of State, Vice-President's Office
Environment