BILLS
SUPPLEMENT No. 14 23rd November, 2012.

BILLS SUPPLEMENT

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Bill No. 18 *National Biotechnology And Biosafety Bill*

THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

MEMORANDUM

1. The object of this Bill is to provide a regulatory framework that facilitates the safe development and application of biotechnology; to designate a national focal point, and a competent authority; to establish a national biosafety committee and institutional biosafety committees; to provide mechanism to regulate research, development and general release of genetically modified organisms and for related matters.

2. Biotechnology refers to any technique that uses living organisms or substances from living organisms to make or modify a product, improve plant, animal breeds or micro-organisms for specific purposes. Biosafety means the safe development, transfer, application and utilisation of biotechnology and its products.

   Biotechnology has been used in Uganda for many years by several industries to process wine and beer, in the production of cheese and yoghurt, leavening bread and extraction of cobalt. However, modern biotechnology which involves the use of genetic engineering techniques to transfer useful characteristics like disease resistance or tolerance to drought, development of medicines, improving the environment is relatively new yet its use creates enormous opportunities for modernisation of agriculture, protection of the environment, enhance public health and industrialisation.

3. At present there is no specific law regulating research, development and use of biotechnology in Uganda. Provisions relating to biotechnology are scattered in laws relating to several sectors, like natural resources conservation and utilisation, industrial development and environmental protection whose administration and management is entrusted to various agencies and departments of Government.

   The Uganda National Council for Science and Technology (UNCST) under the Uganda National Council for Science and Technology Act, Chapter 209 of the Laws of Uganda currently handles the research aspects of modern biotechnology as part of its mandate to regulate research. The existing laws do not explicitly and exhaustively cover issues relating to regulation of modern biotechnology and mechanisms for safe use of biotechnology. Yet enforcement of safe application of modern biotechnology constitutes a core component of a credible national science and technology led economic development and transformation.

4. In addition, in 1993 Uganda ratified the Convention on Biological Diversity (CBD) and subsequently the Cartagena Protocol on Biosafety (CPB) in November 2001 which is the first legally binding international instrument with extensive provisions on the obligations of States on issues of Genetically Modified Organisms (GMOs). Article 2 of the CPB requires Uganda to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol.

5. The Bill therefore seeks to designate and establish institutions that shall regulate and promote the safe development and use of biotechnology in Uganda in order to exploit and promote the use of science and biotechnology in modernising agriculture, protection of the environment, enhancing public health and industrialisation.

6. PROVISIONS OF THE BILL

The Bill has VIII Parts and 4 Schedules.

7. PART I -PRELIMINARY

Clauses 1- 3 deal with the preliminary matters of the Bill. Clause 1 applies the provisions of the Bill to research and general release of Genetically Modified Organisms. Clause 2 provides for the general and specific objectives of the Bill while clause 3 attaches specific definitions to the terms used in the Bill. The Bill defines a Genetically Modified Organism as an organism, or a product consisting of or including an organism, where any of the genes or other genetic material in the organism—

(a) have been modified by means of modern biotechnologies; or

(b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material which were modified.

8. PART II – INSTITUTIONAL FRAMEWORK

Part II deals with the institutions which the Bill proposes should be designated or established, (Clauses 4-14). Under the Cartagena Protocol Uganda is required to designate a National Focal Point to operate as a link between Uganda and the Secretariat for the Convention on Biological Diversity and the Protocol. Clause 4 proposes to designate the Ministry responsible for the environment as the National Focal Point on matters of biotechnology and biosafety.

Clause 6 designates the Uganda National Council for Science and Technology as the Competent Authority for biotechnology and biosafety. This is also in fulfillment of Uganda's obligations under the Cartagena Protocol on Biosafety. The Bill proposes to give UNCST specific functions relating to regulating the development and use of biotechnology including approving research, development and use of GMOs, ensuring safety of biotechnology to human health and the environment during development, testing and use of GMOs, promoting public awareness of biotechnology and biosafety activities and research, (Clause 7).

Due to the cross-cutting multi-sectoral nature of biotechnology, the Bill requires the UNCST to cooperate with other agencies and departments of Government in carrying out its functions. Under clause 8, the Bill proposes that the UNCST should cooperate with the Ministries responsible for agriculture, health, environment, trade, labour and social development, information and communications technology and other relevant agencies in the implementation of the provisions of the Bill.

Clause 9 entrenches the National Biosafety Committee in the law, as a multi-sectoral committee of technical persons to assist the Uganda National Council for Science and Technology to deal with the technical aspects of biotechnology and biosafety.

The Bill proposes that every institution conducting research in Uganda should establish a biosafety committee to process approvals for the initial research and to assist UNCST to supervise the day-to-day research activities at that institution.

9. PART III- RESEARCH AND GENERAL RELEASE OF A GMO
This Part deals with approval for research or general release of a GMO. Clauses 15 - 24 deal with the procedures for applying for approval from the institutional biosafety committee and Uganda National Council for Science and Technology and the review of applications by the technical persons in the National Biosafety Committee. Clause 25 provides for expedited review of applications in specific circumstances to address emergencies or in situations where the applications have been considered by the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety, which is the clearing house for biotechnology applications internationally.

10. PART IV- RISK AND SAFETY ASSESSMENT AND MANAGEMENT
Clause 29 emphasises safety in using biotechnology by providing for measures to be taken to minimise or avoid risk to human health and the environment arising from actual or potential contact with a GMO.

Article 17 of the Cartagena Protocol on Biosafety requires Uganda to provide for emergency measures to deal with unintentional release of a GMO. Clause 30 gives effect to that obligation by requiring every application for research or general release to contain an emergency plan complete with safety measures to cater for circumstances where a GMO is released unintentionally to the environment.

11. PART V - RESTORATION AND CESSATION ORDER
In order to protect the environment from damage arising from biotechnology, this Part enjoins the UNCST with power to issue orders to persons who in the process of conducting biotechnology activities, occasion damage to the environment, to restore the environment to the state it was in before the damage.

12. PART VI- INVESTIGATION AND INSPECTION
Clauses 33 - 36 give power to Uganda National Council for Science and Technology to investigate matters relating to GMO activities for purposes of ensuring compliance with the safety procedures and other provisions of the law and to require a person to remedy any breach in compliance.

13. PART VII- OFFENCES AND PENALTIES
Clauses 37 and 38 provide for the offences and attach penalties in respect of each offence.

14. PART VIII- MISCELLANEOUS PROVISIONS
Clauses 39 - 43 provide for matters which are incidental to the implementation and enforcement of the provisions of the Bill, including appeals, protection of confidential business information made available to officers and staff of UNCST, how to treat biotechnology approvals already granted by UNCST and giving power to the Minister to make regulations in specified circumstances.

MARIA KIWANUKA,
Minister of Finance, Planning and Economic Development.

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THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

ARRANGEMENT OF CLAUSES

Clause

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Clause

A Bill for an Act

ENTITLED

THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY ACT, 2012

An Act to facilitate the safe development and application of modern biotechnology; to designate a national focal point, and a competent authority; to establish a national biosafety committee; to provide for the establishment of institutional biosafety committees; to provide mechanisms to regulate research, development and general release of genetically modified organisms and for related matters.

BE IT ENACTED by Parliament as follows:

PART I—PRELIMINARY

1. Application.

(1) This Act applies to research and general release of a GMO.

(2) For the avoidance of doubt matters related to genetically modified drugs shall be dealt with under the National Drug Policy and Authority Act.

2. Objectives of the Act.

The objectives of this Act are—

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(a) to facilitate the safe development and application of biotechnology;

(b) to facilitate and promote research, development and use of modern biotechnology;

(c) to establish procedures for bio-ethical considerations in biotechnology research;

(d) to strengthen consumer protection and public understanding of products and the benefits of biotechnology;

(e) to facilitate safe use of biotechnology to address national development challenges in food security, healthcare, biodiversity conservation and industrialisation;

(f) to build capacity in biotechnology research, development and innovation;

(g) to promote technology transfer and benefit-sharing in the development and use of modern biotechnology; and

(h) to build strong institutional relationships among biotechnology stakeholders.

3. Interpretation.

In this Act, unless the context otherwise requires—

"advance informed agreement" means the approval given by a competent Authority for a GMO to enter or pass through, its territory;

"biosafety" means the safe development, transfer, application and utilisation of biotechnology and its products;

"biotechnology" means any technique that uses living organisms or substances from living organisms to make or modify a product, improve plant or animal breeds or micro-organisms for specific purposes;

"committee" means the National Biosafety Committee;

"confidential business information" means information which has economic value and the economic value is enhanced by the information being secret;

"confined field testing" means the field testing of a GMO in which physical, biological or other measures are enforced in order to restrict experimental material and genes to the testing site;

"contained testing" means the experimentation of a GMO conducted in an enclosed facility including a glass house or other restricted structure that effectively limit the contact of the GMO with the environment;

"currency point" has the value assigned to it in Schedule 1;

"emergency" means a situation which is urgent or unforeseeable or which is not caused by dilatory conduct where—

(a) Uganda is seriously threatened by or actually confronted with disaster, catastrophe, war or an act of God; or

(b) life or quality of life or the environment may be seriously compromised;

"environment" means the physical factors of the surroundings of human beings, including land, water, atmosphere, climate, sound, odour, taste, the biological factors of animals and plants and the social factor of aesthetics and includes both the natural and the built environment;

"genetically modified organism or GMO" means an organism, or a product consisting of or including such organisms, where any of the genes or other genetic material in the organism—

(a) have been modified by means of modern biotechnologies; or

(b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material which were so modified;

"general release" means the deliberate introduction of a GMO into the environment for the purpose of availing the GMO to other persons or for public use;

"Minister" means the minister responsible for science and technology;

"modern biotechnology" means the application of—

(a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;

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

PART II—INSTITUTIONAL FRAMEWORK

National Focal Point

4. Designation of National Focal Point.

The Ministry responsible for the environment shall be the National Focal Point for the purposes of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

5. Functions of the National Focal Point.

(1) The National Focal Point shall liaise with the Secretariat of the Convention on Biological Diversity.

(2) For the purposes of subsection (1) the National Focal Point shall provide coordinated flow and exchange of information between—

(a) relevant ministries, agencies, and departments on matters concerning the transboundary movement of GMOs;

(b) Governments through formally approved diplomatic channels; and

(c) the Secretariat to the Convention on Biological Diversity and other international organisations, concerning biotechnology and biosafety.

(3) In the performance of its functions, the National Focal Point shall receive information from the Competent Authority regarding biotechnology and biosafety matters in Uganda.

Competent Authority

6. Designation of Competent Authority.
The Uganda National Council for Science and Technology is designated as the Competent Authority for biotechnology and biosafety.

7. Functions of the Competent Authority.
(1) The functions of the Competent Authority are—

(a) to approve the development, testing and use of a GMO in Uganda;

(b) to update and inform the National Focal Point on matters relating to biotechnology and biosafety;

(c) to ensure safety of biotechnology to human health and the environment during development, testing and use of a GMO;

(d) to consider necessary measures to avoid adverse effects on the environment, biological diversity, human health and on socio-economic conditions arising from a GMO;

(e) to establish and maintain a registry and database of biotechnology and biosafety activities;

(f) to prescribe conditions, standards and procedures relating to development, testing , transit and general release of a GMO;

(g) to advise Government on matters of biotechnology and biosafety;

(h) to coordinate the roles of other lead agencies in relation to handling of a GMO;

(i) to promote awareness and education concerning the activities regulated under this Act and to coordinate public participation;

(j) to build capacity in biosafety, and biotechnology research, development and innovation;

(k) to supervise the activities of institutional biosafety committees;

(l) to carry out any other functions as may be incidental for effective implementation of this Act.

(2) In the performance of its functions under this Act the Competent Authority may direct—

(a) an inspector or any other person to destroy a GMO subject to procedures and conditions prescribed by the Minister by Regulations;

(b) any person to stop any activity involving the development, testing or use of a GMO, where the provisions of this Act or the conditions of a permit have not been or are not being complied with.

8. Cooperation with other agencies.

The Competent Authority shall cooperate with other government ministries, departments and agencies in the implementation of this Act.

National Biosafety Committee

9. Establishment of National Biosafety Committee.

(1) There is established a National Biosafety Committee.

(2) The National Biosafety Committee shall consist of the following members—

(a) one person with at least ten years experience in plant or animal breeding, genetics, biotechnology or biosafety who shall be the chairperson;

(b) a representative of the ministry responsible for crop protection with experience and knowledge in phytosanitary matters;

(c) a representative of the ministry responsible for health with knowledge and experience in public health;

(d) a representative of the ministry responsible for the environment with experience and knowledge in biodiversity or ecology;

(e) a representative of the civil society organisations involved in biotechnology and biosafety;

(f) a person with at least ten years experience in sociology;

(g) a representative of the Uganda National Bureau of Standards with experience and knowledge in GMO standards;

(h) a representative of the ministry responsible for justice;

(i) a representative of the private sector;

(j) a representative of the academia or institutions conducting research with knowledge and experience in plant or animal breeding, genetics, entomology, botany, ecology, biotechnology or biosafety;

(k) a representative of farmers nominated by a recognised farmers umbrella association.

(3) The chairperson and members of the committee shall be appointed by the Minister on the recommendation of the Competent Authority.

(4) The Minister shall while appointing the members of the committee ascertain that there is gender balance on the committee.

(5) A member of the committee shall hold office for five years and shall be eligible for reappointment only once.

(6) A member of the committee may resign from office in writing to the Minister or may be removed from office by the Minister where—

(a) the member has been absent from five consecutive meetings of the committee without the permission of the chairperson:

(b) the Minister is satisfied that, the member is unable to discharge the functions of the office due to—

(i) infirmity of the body or mind; or

(ii) for misconduct, or misbehaviour.

(7) Where a member of the committee has resigned or been removed from office, the Minister shall appoint another person.

(8) The members of the committee shall be paid allowances determined by the Minister on the recommendation of the Competent Authority.

10. Functions of the committee.

The functions of the committee are—

(a) to review. and make recommendations on applications received by the Competent Authority;

(b) to advise the Competent Authority on comments received from the public on biotechnology and biosafety;

(c) to recommend to the Competent Authority the amount of fees for processing applications;

(d) to recommend to the Competent Authority mitigation measures to be undertaken in case of an accident or any other issues related to biosafety;

(e) to advise the Competent Authority on the implementation of this Act;

(f) to make recommendations to the Competent Authority on procedures and conduct for risk and safety assessment;

(g) to recommend to the Competent Authority new scientific information in respect of biotechnology and biosafety;

(h) to perform any other function assigned to the committee by the Competent Authority.

11. Business of the committee.

The National Biosafety Committee shall conduct its business in accordance with Schedule 2.

Registrar of biotechnology and biosafety

12. Registrar of biotechnology and biosafety.

(1) The Competent Authority shall by notice in the Gazette, designate an officer not below the rank of assistant executive secretary as the registrar of biotechnology and biosafety.

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(2) A person shall not be designated as registrar unless that person has knowledge and experience in biotechnology and biosafety.

(3) The Competent Authority shall appoint other persons to assist the registrar to carry out his or her functions under this Act.

13. Functions of the registrar.

(1) The functions of the registrar are—

(a) to receive and screen completeness of GMO applications for submission to the committee;

(b) to keep and maintain the register of biotechnology and biosafety activities;

(c) to register all institutions engaged in biotechnology and biosafety research and all matters that are required to be registered under this Act;

(d) to register approved institutional biosafety committees;

(e) to prepare and issue certificates, permits and advance informed agreements after approval by the Competent Authority;

(f) to inspect and monitor any person or activity, permitted, authorised or approved by the Competent Authority and make recommendations to the committee;

(g) to serve notices upon any person to destroy, stop or remove a GMO or any activity related to a GMO or to comply with this Act as directed by the Competent Authority.

(2) The registrar shall in addition to his or her duties specified under this Act be the secretary to the committee.

(3) In the performance of his or her functions under subsection (1), the registrar shall cooperate with other agencies, departments and ministries of government.

14. Institutional biosafety committee.

(1) Every institution registered under this Act shall establish an institutional biosafety committee.

(2) An institutional biosafety committee shall consist of not less than five persons at least three of whom shall have expertise in biosafety.

(3) Two or more institutions registered under this Act may establish a joint institutional biosafety committee.

(4) For purposes of forming an institutional biosafety committee, a research institution registered under this Act may co-opt a person with the relevant expertise.

(5) An institutional biosafety committee established under this section shall be approved by the Competent Authority.

(6) The institutional biosafety committee shall—

(a) approve laboratory experiments and contained testing;

(b) regularly review, monitor and supervise laboratory experiments, contained testing and confined testing;

(c) make recommendations to the Competent Authority in respect of applications for confined testing and general release;

(d) ensure that research is conducted in accordance with this Act, Regulations and guidelines issued by the Competent Authority.

(7) An institutional biosafety committee shall every six months, or when requested by the Competent Authority, in the prescribed manner, make a report to the Competent Authority containing—

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(a) the membership and competence of the institutional biosafety committee:

(b) research approved by the institutional biosafety committee:

(c) activities of the institutional biosafety committee under subsection (6):

(d) the biotechnology and biosafety capacity of the research institution including the human resources and infrastructure.

PART III—RESEARCH AND GENERAL RELEASE OF A GMO

15. Approval of research and general release of a GMO.
A person shall not engage in research or general release of a GMO without approval under this Act.

16. Stages of research.
(1) Research involving a GMO shall be conducted in the following stages—

(a) laboratory experiment; and

(b) testing.

(2) Testing shall be done at the following levels—

(a) contained or greenhouse testing;

(b) confined field testing; and

(c) testing for full safety and risk assessment.

17. Approval for each stage of research.
A person shall before engaging in any stage of research obtain approval as follows—

(a) for laboratory experiment, from the institutional biosafety committee;

(b) for testing—

(i) in the case of contained experiments or green house testing, from the institutional biosafety committee;

(ii) in the case of confined field testing, from the Competent Authority;

(iii) in the case of a full safety and risk assessment, from the Competent Authority.

18. Approval of export, import or transit of a GMO.

(1) A person shall not export, import or transit a GMO without the approval of the Competent Authority.

(2) A person who contravenes this section commits an offence and is liable on conviction to a fine not exceeding one hundred and twenty currency points or imprisonment not exceeding five years or both.

(3) For the purposes of this section, transit means the movement of a GMO through Uganda from the territorial jurisdiction of one country to another.

Procedure for approving research, import, export, transit or general release

19. Laboratory experiment.

(1) A person who wishes to engage in a GMO laboratory experiment shall before commencing the research, notify the institutional biosafety committee of the research institution to which that person is attached.

(2) The notification shall be in Form 1 in Schedule 3 and shall be accompanied by the prescribed fee.

(3) Subject to subsection (4), the institutional biosafety committee shall within twenty one working days respond to the person who notified the institutional biosafety committee under subsection (1), informing the person whether to proceed or not proceed with the experiment.

(4) The institutional biosafety committee shall within seven days after receipt of the notification under subsection (1) notify the Competent Authority of the application.

(5) The Competent Authority may within seven days after receipt of the notice in subsection (4) give directions to the institutional biosafety committee regarding the notification for research.

(6) Where the institutional committee informs the person not to proceed with the experiment, the institutional biosafety committee shall indicate the reasons for the decision.

(7) Where the institutional biosafety committee does not respond to the person within the time specified in subsection (3), the institutional biosafety committee shall be taken to have approved the experiment.

20. Application for approval to conduct contained testing of a GMO.

(1) An application for approval to conduct a contained experiment or greenhouse testing of a GMO shall be made to the institutional biosafety committee in Form 1 in Schedule 3.

(2) The application shall be accompanied by the prescribed fees and shall contain—

(a) the name and address of the applicant;

(b) a detailed description of the laboratory experiment conducted on the GMO in respect of which the applicant is seeking approval for the contained or greenhouse testing;

(c) the location where contained or greenhouse testing activities shall be undertaken;

(d) the nature and identity of the GMOs to be involved;

(e) the nature and purpose of the contained or greenhouse testing activity including storing, transporting, management, disposing or using the GMOs in any other way;

(f) a description of the containment measures to be provided and the suitability of those measures for the GMOs and activities to be undertaken;

(g) a description of any potential risk associated with the GMOs or the activity to be undertaken;

(h) a description of remedial measures to be undertaken in the event of any accident;

(i) a declaration by the applicant that the information contained in the application is correct.

(3) Subject to subsection (4), the institutional biosafety committee shall review the application and respond to the applicant within twenty eight working days.

(4) The institutional biosafety committee shall within seven days after receipt of the application under subsection (1) notify the Competent Authority of the application.

(5) The Competent Authority may within seven days after receipt of the notice in subsection (4) give directions to the institutional biosafety committee regarding the application.

(6) Where the institutional biosafety committee informs the applicant not to proceed with the testing activity, the committee shall indicate the reasons for the decision.

(7) Where the institutional biosafety committee does not respond to the applicant within the time specified in subsection (3), the committee shall be taken to have approved the contained testing.

21. Application for approval to conduct confined field testing of a GMO.

(1) An application for approval to conduct confined field testing of a GMO shall be made to the Competent Authority through the institutional biosafety committee in Form 2 in Schedule 3.

(2) The application shall be accompanied by the prescribed fees and shall contain—

(a) the name and address of the applicant;

(b) a detailed description of the contained or greenhouse testing conducted on the GMO in respect of which the applicant is seeking approval;

(c) the proposed location for the confined field testing activities;

(d) the nature and identity of genetically modified organisms involved in the testing;

(e) the nature and purpose of the confined field testing activities including storing, transporting, producing, processing, disposing or using the genetically modified organisms in any other way;

(f) a description of the confinement measures to be provided and the suitability of those measures for the genetically modified organisms and activities to be undertaken;

(g) a description of any potential risks associated with the genetically modified organisms or the activities to be undertaken;

(h) a description of remedial measures to be undertaken in the event of any accident;

(i) a declaration by the applicant that the information contained in the application is correct;

(j) a recommendation by the institutional biosafety committee.

(3) The National Biosafety Committee shall, when reviewing the application, satisfy itself of availability and suitability of the proposed facility for the safe conduct of the confined field testing.

22. Application for approval for general release of a GMO.

(1) An application for approval of general release of a GMO shall be made to the Competent Authority in Form 3 in Schedule 3.

(2) The application shall be accompanied by the prescribed fees and shall contain—

(a) the name and address of the applicant;

(b) the name and identity of the GMO;

(c) the intended date of the general release;

(d) the taxonomic status, common name, point of collection or acquisition and characteristic of the recipient organism or parental organism related to biosafety;

(e) the centre of origin and centre of genetic diversity of the recipient organism, the parental organism, and the description of the habitat where the organism may persist;

(f) the taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the GMO;

(g) the intended use of the GMO;

(h) the suggested method for the safe handling, storage, transport and use of the GMO.

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(3) The Competent Authority shall within fourteen days after receipt of the application—

(a) send to all ministries and agencies of Government with functions relevant to the application; and

(b) publish in the *Gazette* and the official website of the Competent Authority,

a notice in the prescribed form of the application for general release.

(4) A ministry or agency of Government to which a notice is sent under subsection (3) or any other person may, within thirty days from the receipt of the notice or date of publication of the notice, make any representations to the Competent Authority in respect of the application.

23. Application for import, transit or export of a GMO.

(1) An application for import, export or transit of a GMO shall be in Form 4 in Schedule 3 and shall state the purpose of the import, export or transit.

(2) The application shall, in the case of—

(a) transit, state the destination country and describe the method for safe transportation of the GMO;

(b) importation, be accompanied by an advance informed agreement, and state—

(i) the country of origin;

(ii) the name of the exporter if different from that of the applicant; and

(iii) any approvals of the GMO from the country of origin and any other country.

(c) exportation, state the destination country.

24. Review of applications by National Biosafety Committee.

(1) The Competent Authority shall upon receipt of an application for confined testing, general release, export, import or transit of a GMO, refer the application to the National Biosafety Committee.

(2) The National Biosafety Committee shall review the application and make a recommendation to the Competent Authority, in the case of an application for—

(a) confined testing, within ninety working days;

(b) general release, within two hundred and seventy working days;

(c) export, import or transit, within twenty eight working days.

(3) The Competent Authority shall within ten working days after receipt of the recommendation from the National Biosafety Committee, notify the applicant of its decision.

(4) Where the Competent Authority informs the applicant not to proceed with the testing activity, the Competent Authority shall indicate the reasons for the decision.

25. Expedited review of applications.

The Competent Authority may expedite the review of an application for research or general release of a GMO where—

(a) a competent authority of another country or established at a regional level by multiple countries has previously approved research or general release of the GMO in comparable ecosystems;

(b) a competent authority of another country or established at a regional level by multiple countries has previously established that the research or general release of a GMO poses minimal risk to human health or the environment;

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(c) the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety has exempted the GMO from the advance informed agreement procedures;

(d) the Competent Authority is satisfied that there is an emergency;

(e) the application has previously been considered by the Competent Authority.

26. Conditional approval.

The Competent Authority may approve research or general release of a GMO subject to—

(a) imposing measures, to manage and control adverse effects on the environment, biological diversity, human health and on the socio-economic conditions arising from a GMO;

(b) subjecting the GMO to a specified period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before it is put to its intended use; or

(c) specifying measures to be undertaken by the applicant to minimise risk.

27. Suspension or revocation of approval.

(1) The Competent Authority may suspend or revoke approval given under this Act where the person contravenes the conditions of the approval, or the provisions of this Act.

(2) The Competent Authority shall, before suspending or revoking any approval, give notice in the prescribed manner, specifying the reasons for the revocation or suspension, to the person upon whom the suspension or revocation relates.

(3) The Competent Authority shall invite the person against whom an order is intended to be issued under this section to give reasons, within seven days, why the approval should not be suspended or revoked.

(4) Where the Competent Authority issues a suspension or revocation, it shall publish the suspension or revocation in the *Gazette* and in at least one newspaper with nationwide circulation.

28. Order to stop GMO activities.

The Competent Authority or a person authorised by the Competent Authority may order a person to stop research, general release or any other activity involving a GMO where—

(a) human or environmental safety is compromised;

(b) a person is conducting a GMO activity without or beyond approval; or

(c) additional scientific or technical information relating to the adverse effect of the GMO activity has become available.

PART IV—RISK AND SAFETY ASSESSMENT AND MANAGEMENT

29. Risk and safety assessment.

(1) Every applicant shall carry out an assessment of any risk associated with a GMO and submit a risk and safety assessment report in the case of—

(a) laboratory research and contained testing, to the institutional biosafety committee;

(b) general release and confined testing, to the Competent Authority.

(2) The institutional biosafety committee or the Competent Authority shall evaluate the risk associated with the GMO in accordance with the prescribed safety standards.

(3) The institutional biosafety committee or the Competent Authority shall not approve an application, where the evaluation shows that the risk cannot be avoided or mitigated.

(4) The risk and safety assessment shall be carried out in accordance with Schedule 4.

30. Unintentional release and emergency measures.

(1) An institutional biosafety committee or the National Biosafety Committee shall before recommending an application for approval for research or general release ensure that the application contains—

(a) an emergency plan which includes information on safety measures and procedures to be adopted in the case of any unintentional release; and

(b) mechanisms through which the information shall be made available to the persons likely to be affected by the unintentional release.

(2) Where there is unintentional release of a GMO, the applicant or person to whom approval was given shall within twenty four hours inform the Competent Authority about the unintentional release providing the following information—

(a) the circumstances of the accident;

(b) the identity and quantity of GMO released unintentionally;

(c) any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) the mitigation measures taken.

(3) The Competent Authority shall take appropriate measures to mitigate the risk arising out of the unintentional release.

PART V—RESTORATION ORDERS

31. Restoration order.

(1) The Competent Authority may issue a restoration order—

(a) where a person conducts an activity relating to a GMO without or beyond the approval of the Competent Authority;

(b) in the case of damage caused by the unintentional release of a GMO attributable to that person;

(c) where the Competent Authority has issued an order to the person to stop research or general release of a GMO;

(d) in any other case where the activity of a person has caused damage.

(2) A restoration order issued under subsection (1)—

(a) shall direct the person to whom it is addressed to restore the conditions as near as they may be to the state in which they were before the release of the GMO;

(b) may levy a charge on the person on whom it is served which, in the opinion of the Competent Authority, represents a reasonable estimate of the cost of any action taken by an authorised person to restore the environment to the state in which it was before the release of the GMO.

32. Contents of restoration order.

The Competent Authority shall specify in the restoration order—

(a) the activity to which the order relates;

(b) the person to whom the order is addressed;

(c) the action which should be taken to remedy the damage and the time, being not more than thirty days or such further period as may be prescribed in the order, within which the action shall be taken; and

(d) the penalty which may be imposed if the action specified is not taken.

33. Investigation of complaints.

The Competent Authority may investigate any matter within its functions under this Act which relates to research or general release of a GMO.

34. Appointment of inspectors.

(1) The Competent Authority may by notice in the *Gazette* appoint inspectors for the purposes of ensuring compliance with this Act and the directives of the Competent Authority.

(2) An inspector shall, when exercising powers under this Act, produce the instrument of appointment and identification when required to do so by any person.

35. Powers of an inspector.

(1) Subject to subsection (2), an inspector may enter and inspect at any reasonable time, a place owned by or under the control of a person conducting research or general release of a GMO—

(a) in which the inspector believes on reasonable grounds to be any document, information or article relevant to the enforcement of this Act and examine the document, information or article or remove it for examination or reproduction;

(b) where the Competent Authority is satisfied that the level and magnitude of activities conducted in a facility might adversely affect the environment and human health.

(2) An inspector may seize, quarantine or otherwise stop the sale of a GMO that was released or imported in violation of this Act.

(3) The inspector shall sign for any information, document, article or equipment removed by the inspector under this section and shall leave a copy of the signed record with the person conducting research or general release.

(4) Where a place referred to under subsection (1) is a dwelling house, an inspector shall not enter that dwelling house without the consent of the occupant, unless—

(a) under the authority of a warrant issued by a court;

(b) by reason of exigent circumstances, it would not be practical for the inspector to obtain a warrant.

(5) For the purposes of subsection (4) (b), "exigent circumstances" means circumstances in which the delay arising from obtaining a warrant would result in danger to human life or safety.

36. Direction to remedy breach.

Where as a result of an investigation the Competent Authority is satisfied that a person has breached a condition of the approval or an obligation under this Act, it may direct that person in writing to remedy the breach or issue a restoration order under section 31.

PART VII—OFFENCES AND PENALTIES

37. Offences and penalties.

Any person who—

(a) engages in research or makes general release of a GMO without approval commits an offence and is liable on conviction to a fine not exceeding one hundred and twenty currency points or imprisonment not exceeding five years or both;

(b) fails to disclose any information as required by this Act commits an offence and is liable on conviction to a fine not exceeding forty eight currency points or imprisonment not exceeding twenty four months or both;

(c) furnishes false information commits an offence and is liable on conviction to a fine not exceeding forty eight currency points or imprisonment not exceeding twenty four months or both;

(d) releases or uses any confidential information for any purpose not authorised under this Act commits an offence and is liable on conviction to a fine not exceeding fourty eight currency points or imprisonment not exceeding twenty four months or both;

(e) uses a GMO in a manner inconsistent with the approval granted under this Act commits an offence and is liable on conviction to a fine not exceeding twenty four currency points or imprisonment not exceeding twelve months or both;

(f) uses a GMO to deliberately harm or injure the environment or human health commits an offence and is liable on conviction to a fine not exceeding two hundred and forty currency points or imprisonment not exceeding ten years or both;

(g) obstructs the Competent Authority or an officer of the Competent Authority from the performance of their duties under this Act commits an offence and is liable on conviction to a fine not exceeding twenty four currency points or imprisonment not exceeding twelve months or both;

(h) neglects, refuses or fails to take emergency safety measures in case of unintentional release of a GMO commits an offence and is liable on conviction to a fine not exceeding one hundred and twenty currency points or imprisonment not exceeding five years or both.

38. Offence by a body corporate.

Where an offence under section 37 is committed by a body corporate—

(a) every director and officer of that body corporate shall also be taken to have committed that offence; and

(b) where the body corporate is a firm, every partner of that firm shall also be taken to have committed that offence.

unless he or she proves that the offence was committed without his or knowledge or that he or she exercised due diligence to prevent the commission of the offence.

PART VIII—MISCELLANEOUS PROVISIONS

39. Protection of confidential business information.

(1) The Competent Authority and institutional biosafety committee shall protect confidential business information submitted by an applicant and shall not disclose confidential information except with the written consent of the applicant.

(2) The Competent Authority shall—

(a) permit the applicant to identify information submitted that is to be treated as confidential, with justification for claims of confidentiality to be given upon request;

(b) inform the applicant if it decides that information identified by the applicant as confidential does not qualify for the treatment;

(c) prior to any disclosure of information, inform the applicant of its decision, providing reasons upon request, as well as an opportunity to appeal the decision prior to disclosure;

(d) where an applicant withdraws an application or does not get approval, respect the confidentiality of the commercial and industrial information, including research and development information, as well as information on which the Competent Authority and the applicant disagree as to its confidentiality.

(3) For the purposes of this section (1) the following information shall not be considered confidential—

9.

(a) name and address of the applicant;

(b) a summary description of the GMO and its purpose ;

(c) a summary of any risk and safety assessments; and

(d) methods and plans for emergency response.

40. Protection from personal liability.

A member of the Council or staff, of the Competent Authority or a person authorised by the Competent Authority shall not, be personally liable for any act or omission done bona fide in the execution of the functions, powers or duties of the Competent Authority, under this Act.

41. Appeals.

(1) A person aggrieved by the decision of an institutional biosafety committee may within fourteen working days appeal to the Competent Authority.

(2) A person aggrieved by the decision of the Competent Authority may appeal to the Minister within twenty one working days.

42. Transitional provisions.

Approval given by the Uganda National Council for Science and Technology for research or general release of a GMO before the commencement of this Act shall be taken as given by the Competent Authority under this Act.

43. Amendment of Schedules.

(1) The Minister may, with the approval of Cabinet, by statutory instrument, amend Schedule 1.

(2) The Minister may on the recommendation of the Competent Authority by statutory instrument amend Schedules 2, 3 and 4.

44. Regulations.

(1) The Minister may, after consultation with the Competent Authority, make regulations for the purposes of carrying into effect the provisions of this Act.

(2) Without prejudice to subsection (1) the Minister may after consultation with the Competent Authority make regulations—

(a) prescribing procedures for research involving genetically modified organisms;

(b) prescribing the procedures for general release of genetically modified organisms into the environment;

(c) for handling, transport, identification, and packaging of genetically modified organisms;

(d) specifying the fees for applications and other services under this Act;

(e) specifying the safety levels and standards for safety of GMOs;

(f) establishing procedures for bio-ethical considerations in biotechnology research;

(g) prescribing penalties in respect of any contravention of the regulations not exceeding a fine of forty eight currency points or imprisonment not exceeding twenty four months or both; and

(h) for the better carrying into effect the provisions of this Act.

SCHEDULE 1

section 3

CURRENCY POINT

One currency point is equivalent to twenty thousand shillings.

SCHEDULE 2

Section 11

Conduct of business and affairs of the National Biosafety Committee

1. Meetings of the committee.

(1) The chairperson shall convene meetings of the National Biosafety Committee at times and places as the committee may determine, and the committee shall meet for the discharge of business at least once every three months.

(2) The chairperson may, at any time, convene a special meeting of the committee and shall call a meeting within fourteen days, if requested to do so in writing by at least four members of the committee.

(3) Notice of a meeting of the committee shall be given in writing to each member at least seven working days before the day of the meeting.

(4) The chairperson shall preside over every meeting of the committee and in the absence of the chairperson, the members present shall appoint a member from among themselves to preside at that meeting.

2. Quorum.

(1) The quorum for a meeting of the committee is seven members of the committee.

(2) All decisions at a meeting of the committee shall be by a majority of the votes of the members present and voting, and in case of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to his or her deliberative vote.

3. Minutes of meetings.

(1) The registrar shall record and keep, minutes of all meetings of the committee in a form approved by the committee.

(2) The minutes recorded under this paragraph shall be submitted to the National Biosafety Committee for confirmation at its next meeting following that to which the minutes relate and when so confirmed, shall be signed by the chairperson, in the presence of the members present at the latter meeting.

4. Power to co-opt.

(1) The committee may invite any person who, in the opinion of the committee, has expert knowledge concerning the functions of the committee, to attend and take part in the proceedings of the committee.

(2) A person attending a meeting of the committee under this paragraph may take part in any discussion at the meeting on which his or her advice is required but shall not have any right to vote at that meeting.

5. Validity of proceedings not affected by vacancy.

The validity of any proceedings of the committee shall not be affected by a vacancy in its membership or by any defect in the appointment or qualification of a member or by reason that a person not entitled, took part in its proceedings.

6. Disclosure of interest of members.

(1) A member of the committee who is in any way directly or indirectly interested in any matter which fails to be considered by the committee, shall disclose the nature of his or her interest at a meeting of the committee.

(2) A disclosure made under subparagraph (1) shall be recorded in the minutes of that meeting.

(3) A member who makes a disclosure under subparagraph (1) shall not—

(a) be present during any deliberation of the committee with respect to that matter; or

(b) take part in any decision of the committee with respect to that matter.

(4) For purposes of determining whether there is a quorum, a member withdrawing from a meeting or who is not taking part in a meeting under subparagraph (3) shall be treated as being present.

7. Committee may regulate its procedure.

Subject to this Act, the committee may regulate its own procedure or any other matter relating to its meetings.

SCHEDULE 3

Section 20

FORMS

FORM 1

Notification of laboratory experiment involving GMOs / application for approval to conduct contained testing of GMOs

The National Biotechnology and Biosafety Act, 2012

NOTIFICATION OF LABORATORY EXPERIMENT INVOLVING GMOs / APPLICATION FOR APPROVAL TO CONDUCT CONTAINED TESTING OF GMOs

PART A- PARTICULARS OF APPLICANT

1. Name.....
2. Address
   - (a) Physical.....
   - (b) Postal.....
   - (c) Telephone,..... Fax.....
   - (d) Email.....

PART B—PARTICULARS OF RESEARCH

3. Title of proposed research activity.....
4. Summary of proposed research activity.....
5. Categorisation of data
   - a) Source of nucleic acid.....
   - b) Specification of nucleic acid sequence.....
   - c) Vector host system.....
   - d) Restriction map.....
   - e) Genetic manipulation procedures.....
   - .....
   - .....

[1]For laboratory research involving GMOs, the applicant shall complete this form as a notification form. Where permission to proceed with contained research is desired, this form shall serve as the application form.

6. Plan of investigation.....
.....
.....
.....

7. Description of proposed physical containment measures.....
.....
.....
.....
.....
.....

8. Describe proposed biological containment measures.....
.....
.....
.....

9. Description of the subsequent use (if any) or distribution(if any) of the recombinant DNA materials.....
.....
.....
.....

10. Source of financial support for the research activity.....
.....
.....

11. Names and addresses of persons proposed to be involved in the
    (a) .....address.....
    (b) .....address.....
    (c) .....address.....

12. Description of the training steps taken to ensure that the persons proposed to be involved in the research are familiar with relevant biosafety laws, guidelines, and laboratory procedures involved with GM work
.....
.....

13. Describe the arrangements made for health and environment monitoring

.....

.....

PART C- FACILITIES FOR RESEARCH

14. Name of facility.....

15. Location.....

.

16. Description of the nature of the research facility .....

.....

.....

17. Do you have approval to use the facilities, YES NO

DECLARATION

I declare that the information provided in this form is accurate to the best of my knowledge.

Dated this.....day of.....20..'

(Signed).....

Applicant/person making notification.

18. Recommendation of Head of Department/Unit/Programme/ Authorised official.....

.....

.....

FORM 2

Section 19, 21

Application for approval to conduct confined testing of a GMO in Uganda.

The National Biotechnology and Biosafety Act, 2012

APPLICATION FOR APPROVAL TO CONDUCT CONFINED TESTING OF GMOs IN UGANDA

To : The Competent Authority

1. General Information

i. Name of the Applicant (Principal Investigator)

ii. Position

iii. Institutional Address

iv. Department /Division/ Programme

v. Telephone (office): Mobile: Fax:

vi. E-mail:

vii. Title of the proposed confined testing research

viii. Proposed date of commencement of the confined testing research

ix. Proposed date of completion of the confined testing research:

x. Name all the institutions both national and International that are involved in this work, giving their full contact addresses, including physical, email, and telephone addresses of the contact persons in these institutions

a. National:

b. International:

xi. Do you have funding commitment for this project?

Yes No

xii. What is/are your external and internal funding agency (ies) or source(s)?

xiii. Attach a complete proposal for the confined testing research that should include a budget.

2. Specific Information:

i. Were/are any of the following genes, viruses, factors, or conditions involved in the work? *(answer yes or no)*

a. Deliberate transfer of drug resistance into organisms that do not acquire them naturally? (except for approved host-vector systems that contain antibiotic resistance markers)

b. Deliberate transfer of DNA into humans?

c. Deliberate formation of DNA-containing genes that produce vertebrate toxins with LD50 less than 100ng/kg of Body weight?

d. Using animal or human pathogens (Risk Groups 2-4 and restricted agents) as host vector systems?

e. Using human or animal pathogen DNA cloned into non-pathogenic prokaryote or lower eukaryote host-vector systems?

f. Using infectious animal or plant DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems? (work with animal pathogens requires a sanitary certificate and an import permit from the relevant government agency(ies)

g. Altering an animal genome by recombinant DNA or testing viable DNA modified microorganisms in whole animals?

h. Experiments involving restricted and controlled release of DNA modified plants or animals

i. *Give an explanation of your answers in A (a-h) above wherever it was a* ***Yes*** *indicating clearly which of the subsections a-h you are referring to*

ii. Description of the confined testing research (Please provide a brief project description including objectives, methodology and time frame of the different research activities):

iii. Host organism (List the Biosafety Level where applicable, name and taxonomic classification)

iv. Describe the vector(s) used and their sources

v. **Personnel**- Apart from the Principal Investigator (PI)of the confined testing research, list the names and titles of all the other individuals that will be engaged in the experiments beginning with the research manager for the confined testing. Attach abridged curriculum vitae (not more than one page) for the PI as well as those of the other personnel to be involved with the research activities (not more than half a page each).

vi. What arrangements do you intend to put in place for effective health and environment monitoring

vii. **Training**- Indicate the steps taken or to be taken to ensure that personnel identified above are familiar or will be familiar with relevant biosafety procedures established by the government of Uganda and other international authorities. Evidence of the training shall be provided to the Competent Authority prior to establishment of the confined testing experiment.

viii. Briefly describe the proposed locations of the confined testing research in broad terms such as district, county sub-county, village.

ix. State whether the necessary permission has been secured for use of proposed confined testing locations

3. Information on the organism

a. Unmodified organism information

i. Name of the unmodified organism (common and scientific names)

ii. Describe the reproductive mechanisms of the organism (Attach any additional information on the biology of the organism)

iii. Is Uganda a primary centre of diversity or origin of the species of the organism? Yes No

iv. Is Uganda a secondary centre of diversity for the organism? Yes No

v. Is the organism considered naturally invasive?

Yes No

If Yes, please describe

b. Modified Organism Information:

i. Describe the genetic modification that was done to the organism.

ii. Has genetic modification altered the reproductive biology of the organism? Please explain

iii. Does the introduced genetic material give rise to any infectious agents?

iv. Has the genetically modified organism been tested or commercially released in Uganda or elsewhere? Please explain

v. Early efficacy data: Describe results of tests of the expression and efficacy of the target phenotype from the laboratory, containment and confined testing stages, as applicable.

vi. Has another country rejected an application for the planned confined testing of this GMO or genetic event? If so, which country and on what basis?

vii. Provide an annex of information for each genetic element (or feature) of the construct including coding sequences, promoters, enhancers, termination and polyadenylation signal sequences, and their source organism, involved in the confined testing research (Please clearly indicate confidential business information, justifying why it is confidential, such that it is considered for keeping confidential by the institutional biosafety committee, national biosafety committee, and the Competent Authority)

viii. Provide an annex or a thorough description of the method of transformation used; specify the selectable marker(s) used, clarifying on the safety of the marker(s)

c. **Material and Genetic Confinement:**
Measures to minimise gene flow from the confined testing, persistence of GMO material in the environment, or entry of material into the food or feed pathways.

i. Provide information on the proposed confined testing site size and location, surrounding areas and geographic features as well as the proposed isolation of the testing site (*a map of the proposed site and associated permanent structures must also be attached*).

ii. Are there any sexually compatible wild relatives of the GMO in Uganda? Yes No

If yes, Describe them:

iii. If yes, are these within the vicinity of the confined testing site?

iv. Describe the mechanisms you intend to use to minimise gene flow justifying each of the mechanisms proposed.

For instance:

- Isolation distances
- Removal of reproductive parts
- Temporal isolation
- Termination of experiment before sexual maturity
- Measures to prevent progeny dispersal from the test area
- Any other mechanism as may be applicable

(Include and describe climatic and geo-physical data that may influence the reproductive isolation methods suggested).

v. Type of data to be collected and method of record keeping? (*record keeping must be consistent which the requirements of the confined testing and/or according to the requirements set by the Competent Authority*).

vi. Describe how the genetically engineered organism material will be packaged for transport to the confined testing site.

vii. Describe how the packaging material will be cleaned and/ or disposed after use.

viii. Describe how the packaging material containing the genetically engineered material will be marked/ identified during the transportation to the confined testing site.

ix. Describe measures to inhibit unauthorised removal of material from the confined testing site: These may include but are not limited to fencing, guarding, locked gate or locating the confined testing experiment in an adequately isolated area.

x. What additional measures, if any, shall be taken to minimise and possibly preclude local fauna and humans from removing material from the confined testing site?

xi. Describe how surplus testing material will be recorded and disposed at the site.

94

xii. Describe how equipment used in the establishment of the confined testing research will be cleaned.

xiii. Describe the training that will provided personnel regarding measures to ensure material confinement.

xiv. How will the materials be collected from the testing site after the experiment is concluded?

xv. Will any of the collected material from the testing site be retained and if so, for what purpose and under what transport and storage conditions?

xvi. How will the collected materials and residues be disposed?

xvii. Will material be removed away from the confined testing site for further analysis? Yes No

If yes, explain how these will be used and destroyed.

xviii. Describe the post-testing plans to control proliferation of the GMO on the testing site after removal of materials. The description should give reference to the following:

- Biodiversity patterns on the site;
- Duration of monitoring;
- Frequency of monitoring;
- Disposal of any identified progenies;
- Any other means; and,
- Record keeping.

d. Contingency Plans

Describe your contingency plans in the event of accidental release of genetically engineered organism material. The description should make reference to notification of the authorities, recovery of the material, confinement of the material, and to any other measures that may be employed.

4. DECLARATION

a. Declaration by the applicant

I hereby declare that the information provided in this application is complete and accurate. I am familiar with and agree to abide by the relevant provisions of the National Biotechnology and Biosafety Act, regulations, guidelines and other specific instructions from the institutional biosafety committee and the Competent Authority, and any other regulatory requirement as far as implementation of the proposed confined testing is concerned. No elements in my research will be implemented without prior review and approval by the institutional biosafety committee and the Competent Authority as the case may be.

Name:_____

Signed:_____ Date:_____

Profession _____

b. Institutional biosafety committee recommendation

i. Comment on the suitability of the premises, staff capacity, resources and authenticity of the information given in this application.

ii. Briefly explain how and at what frequency will the institutional biosafety committee monitor the activities of the proposed confined testing experiment, giving approximate time intervals at which the institutional biosafety committee will furnish the Competent Authority with reports about this research (except for emergencies that must be reported within the shortest time possible).

iii. Provide a list of names and addresses of all members of the institutional biosafety committee indicating those that were involved in reviewing this application.

c. **Declaration by the institutional biosafety committee chairperson or biosafety officer/secretary to institutional biosafety committee**

I declare that the proposal set out in this application has been considered by a properly constituted institutional biosafety committee of which I am the authorised representative and whose views on the proposal are accurately set out in Section 4 (b) of this form.

Name:_____

Signed:_____Date:_____

Title with respect to the institutional biosafety committee_____

Section 20

FORM 3

Application for approval to make a general release of GMOs in Uganda

The National Biotechnology and Biosafety Act, 2012

APPLICATION FOR APPROVAL TO MAKE A GENERAL RELEASE OF GMOs

PART A—PARTICULARS OF APPLICANT

a. Name.....

b. Address

(a) Physical.....

(b) Postal.....

(c) Telephone,..... Fax.....

(d) Email.....

PART B – PARTICULARS OF THE GENERAL RELEASE

2.1 Proposed date of the general release.....

2.2 Proposed location for the general release.....

2.3 Estimated amounts of GMO material to be produced annually, including amounts to be released directly by the person making the general release.....

2.4 Names and addresses of the agents, where the general release is proposed to be made through agents .....

.....

.....

2.5 Details of the recommended packaging, transportation, storage and handling methods for the GMO.....

2.6 Details of the type of environment and the geographical areas for which the non modified organism is suited.....

2.7 Describe any previous general releases of the GMO in other countries, where applicable .....

2.8 State whether a similar application for general release of the GMO has ever been made and rejected in another country, detailing reasons for the rejection where applicable.....

PART C—DESCRIPTION OF THE GENETICALLY MODIFIED ORGANISM

3.1 Briefly describe the taxonomic status, common name, point of collection or acquisition and characteristic of the recipient organism or parental organism related to biosafety.....
.....

3.2 Describe the trait of the genetically modified organism.....
.....
.....

3.3 Identify all genes introduced in the GMO.....

3.4 Describe the gene products that are derived from the introduced genes.....
.....

3.5 Describe the biological activity associated with the new gene products.....
.....

3.6 Describe the rate and level of expression of the new genetic material, method and sensitivity of measurement.....
.....

3.7 Describe identification and detection techniques of the introduced gene sequences (include sensitivity, reliability and specificity of the techniques).....
.....

3.8 Describe the characteristics of the vector used, including its identity, sources(s) or origin.....
.....

PART D—INFORMATION ON THE PRODUCT(S) DERIVED FROM THE GMO

4.1 Identify the part of the GMO to be used for the product

4.2 Describe the type of product, the intended use, and the targeted communities (e.g *farmers, children, women, etc.*).....

.....

4.3 Briefly describe the rationale for using genetic engineering to avail the product .....

.....

4.4 Information on the proposed identification of the product marketing.....

4.5 Describe, where applicable, previous uses of the product(s) from GMO in other countries and environments.....

.....

.....

4.6 List other potential uses of the GMO product(s) other than the intended use.....

.....

.....

4.7 Describe the specific storage and handling of viable GMO material that will avoid misuse or escape of the genetic material into the for which it is not intended.....

.....

PART E – SUMMARY OF FIELD TESTING IN RESPECT OF THE GMO

5.1 Give a brief description of any confined testing field experiments conducted in respect of the GMO in

(a) Uganda .....

(b) Other country.....

926

5.2 Provide data on the field performance of the GMO, indicating the locations, dates, efficacy of the introduced traits, and the overall field performance of the GMO.....

.....

PART F—SUMMARY OF REPRODUCTIVE BEHAVIOUR OF THE GMO

6.1 Briefly describe the reproductive biology of the GMO, including sexual and asexual systems where applicable (where available, attach annex of consensus or published reproductive behaviour of the GMO from reputable organisations or authorities).....

6.2 List the measures to limit cross reproduction of the GMO with related un-modified relatives.....

.....

6.3 Describe the biological dispersal mechanisms for the GMO, including artificial dispersal systems (such as distribution and planting of crop seeds).....

6.4 Identify any organism in the area of general release that may become cross-fertilised with the genetically modified pollen.....

6.5 Describe known measures of limiting biological dispersal of the genetic material to unintended environments.....

6.6 Describe the nature of material to propagate the GMO.....

6.7 If biological dispersal occurs, describe the quantities of reproductive parts of the GMO that are likely to be dispersed and how the reproductive parts shall interact in the environment, including any long term effects.....

PART G – SAFETY TO HUMAN AND ANIMAL HEALTH

7.1 Will the GMO enter the human and livestock feed chain? (Answer Yes or No)

7.2 If yes above, describe the food and feed safety testing results in respect of the foreign gene products (including marker genes) to humans and animals, information should include: mode of function, toxicity studies, previous uses in the food and feed chain, intended effects, an assessment of the amino acid similarity between the introduced or new gene and known allergens and toxins.....

7.3 Describe any common or major allergens present in the recipient organism before modification

7.4 State whether the genetic modification described in this application resulted in over-expression of the possible allergens indicated in this Part.

7.5 Describe the overall stability of the new gene products regarding enzymatic degradation using appropriate *in vitro* assays.....

7.6 Where there is known adverse toxicity of the introduced gene product to humans and animals, describe the mechanisms to limit the contact of the GMO to humans and animals.....

7.7 In the event that the GMO is not intended to enter the food and feed chain, describe the management systems to ensure that the GMO does not enter the food and feed chain.....
.....

7.8 What are the effects of the undertaking with regard to the health and safety of the workers and any other person that will directly or indirectly b involved in the general release.....

7.9 Describe the health and safety measures that shall be applied to safeguard employees during the proposed general release.....

PART H – SAFETY TO THE ENVIRONMENT

8.1 Describe any potential long-term effects the GMO may have on the environment to which the general release is intended including effects on the following:

i. Biological diversity.....

ii. Biotic and Abiotic components of the environment.....

8.2 Describe how the effects 8.1 shall be managed.....

8.3 Describe measures to limit spread of the GMO to un-intended environments.....

92C

8.4 Where the GMO has been specifically developed to elicit resistance to specific biotic or abiotic components of the environment, state whether the resistance is likely to break down.....

8.5 Describe measures to limit the possibility of resistance breaking down as describe in section 8.4 .....
.....

8.6 Describe how resistance shall be managed in the environment during general release of the GMO.....

8.7 Where the GMO requires the deliberate use of specific chemicals and compounds to attain the intended value, give details of the environmental safety of the chemicals and compounds.....

8.8 Describe the methods for environmental monitoring of the GMO, including measures for emergency procedures in the event of adverse reaction in the environment.....

8.9 Where only selected parts or products of the GMO will be used, describe methods for the safe disposal of the un-used parts or bi-products of the GMO.....

8.10 Attach an evaluation of the foreseeable pathogenic or ecological disruptive impacts.....

PART I – SOCIO-ECONOMIC CONSIDERATIONS

9.1 List any potential positive or negative socio-economic effects of the proposed general release activity in Uganda or within the target population

9.2 Identify any possible bio-ethical aspects of the general release activity

9.3 Suggest measures to limit any potential negative socio-economic or ethical considerations

PART J - DECLARATION

10.1 I declare that the information provided in this form is accurate to the best of my knowledge.

Dated this.....day of.....20..

(Signed) .....

(Name) .....

Applicant

10.2 Recommendation of authorised official representative of the institution making the general release (*examples are directors, managers, heads of departments, etc.*) .....

PART K – RISK ASSESSMENT FORMAT FOR GENERAL RELEASE OF GMOS IN UGANDA

11.1 Name, institution, address of applicant.....

11.2 Name(s), institution(s) and address(s) of risk assessment team, where applicable.....

11.3 Title of risk assessment.....

11.4 Information on recipient organism or parental organisms. Describe, to relevant detail, the biological characteristics of the recipient organism or parental organisms, including information ontaxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate.....

11.5 Point of collection or acquisition of recipient or parental organism.....

11.6 Characteristics of receipt organism or parental organism related to biosafety

(a) sexual compatibility with other wild species, including the distribution in Uganda of those species.....

(b) Survivability

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability.....

(c) dissemination

(i) ways and extent of dissemination, e.g estimation of how viable propagules declines with distance

(ii) specific factors affecting dissemination

(d) geographical distribution of the GMO.....

92d

(e) Other potential interactions, relevant to the GMO in the ecosystem where it is usually propagated or elsewhere including information on toxic effects on humans, animals and other organisms.....

(f) wild species.....

11.7 Information on donor organism or organisms. Detail the taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms.....

11.8 Vector. Describe the characteristics of the vector, including its identity, if any, and its source or origin, and its host range.....

11.9 Insert or inserts or characteristics of modification. Describe the Genetic characteristics of the inserted nucleic acid and the function it specifies, or characteristics of the modification introduced.....

.....

11.10 Living modified organism. Give a description of the identity of the GMO, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

11.11 Detection and identification of the GMO. List the suggested detection and identification methods and their specificity, sensitivity and reliability.....

11.12 Information relating to the intended use. Provide information relating to the intended use of the GMO, including new or changed use compared to the recipient organism or parental organisms.....

11.13 Receiving environment. Provide information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.....

11.14 Estimation of risk. Provide an estimate of the likelihood of adverse effects on human health and environment, following procedure in Schedule 4 of the Act....

11.15 Provide any additional risk assessment studies relevant to the application for the general release.....

Form 4

NATIONAL BIOTECHNOLOGY AND BIOSAFETY ACT 2012

APPLICATION FORM FOR IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS

1. Name, address *(including physical address)* and contact details of the importer/exporter.....
2. Type of application *(Tick as appropriate)*

   Import

   Export

   Transit
3. Importing / destination country.....
4. Exporting country.....
5. Expected date of import/export/transit.....
6. Brief description of the GMO.....
7. Port of entry into Uganda.....
8. Port of exit from Uganda in case of transit or export.....
9. Regulatory status of the GMO in country of origin .....
10. Description of previous approvals of the GMO in Uganda for transit / import / or export.....
11. Consent of import from destination country in case of transit.....
12. Description of the intended use of the GMO in Uganda in case of import .....
13. Quantity or volume of the GMO to be imported into /transited through/ exported from Uganda.....
14. Summary description of previous or current risk assessments conducted.....
15. Description of the suggested methods for safe handling, transport, packaging, labeling, disposal, and storage of the GMO.....

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16. Suggested emergency response measures in the event of unintentional releases.....

17. DECLARATION BY APPLICANT:

I hereby declare that the information provided in this application is complete and accurate. I am familiar with and agree to abide by the relevant provisions of National Biotechnology and Biosafety Act and regulations.

Dated this.....day of.....20...

(Signed) .....

(Name) .....

Applicant

SCHEDULE 4

Section 29 (4)

RISK AND SAFETY ASSESSMENT

1. Objective of conducting risk and safety assessment.
The risk and safety assessment shall be conducted with the objective of identifying and evaluating the potential adverse effects of a GMO on human health and the environment.

2. Use of risk and safety assessment.
The Competent Authority shall not approve general release of a GMO unless it is satisfied that a risk and safety assessment has been conducted in respect of the application.

3. General principles.
Risk and safety assessment shall be conducted according to the following principles—

(a) risk and safety assessment shall be carried out in a scientifically sound and transparent manner and may take into account expert advice, standards and guidelines developed by relevant organisations.

(b) lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk;

(c) risk associated with a GMO shall be considered in the context of the risks posed by—

(i) the non-modified recipient; and

(ii) the parental organisms,

in the potential receiving environment.

4. Procedure for conducting risk and safety assessment.
Risk and safety assessment shall be conducted according to the following steps, as appropriate—

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(a) an identification of any genotype and phenotypic characteristics associated with the GMO that may have adverse effects on the environment or on human health;

(b) an evaluation of the likelihood of these adverse effects being realised, taking into account the level and the kind of exposure of the likely potential receiving environment of the GMO;

(c) an evaluation of the consequences should these effects be realised;

(d) an estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;

(e) a recommendation as to whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks; and

(f) where there is uncertainty regarding the level of risk, the Competent Authority may request for further information on the specific issues of concern or may recommend implementing appropriate risk management strategies and monitoring the GMO in the receiving environment.