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THE REPUBLIC OF UGANDA

THE NATIONAL BIOSAFETY ACT, 2017.

Bio technology - Genetic Engineering

THE REPUBLIC OF UGANDA

I SIGNIFY my assent to the bill.

.....

President

Date of assent:.....

THE NATIONAL BIOSAFETY ACT, 2017

ARRANGEMENT OF SECTIONS

section

Section

THE REPUBLIC OF UGANDA

THE GENETIC ENGINEERING AND BIOSAFETY ACT

THE NATIONAL BIOSAFETY ACT, 2017.

A new long title

An Act to facilitate the safe development and application of biotechnology; to designate a National Focal Point, and establish a Competent Authority; to establish the Inter-Ministerial Policy Committee on ~~Biotechnology~~ Genetic Engineering and Biosafety; 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.

DATE OF ASSENT:

Date of Commencement:

BE IT ENACTED by Parliament as follows:

PART I—PRELIMINARY

1. Application.

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

Address the concerns of the President.

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

Add a new clause on the applicability of the law to Human cloning.

(3) This Act shall not apply to Human Cloning.

2. Objectives of the Act.

The objectives of this Act are—

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

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

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

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

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

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

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

(h) to build strong institutional relationships among Genetic Engineering ~~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;

Genetic Engineering "~~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; →

Consequential amendment.

Council means the

"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

Genetic Engineering → (1) Modern biotechnologies

(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~~ Genetic Engineering" 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 science, technology and innovation 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~~ Genetic Engineering and biosafety.

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

Competent Authority

6. Establishment of Competent Authority.

(1) There is established within the ministry responsible for Science, Technology and Innovation, a Directorate responsible for biosafety, for purposes of implementing this Act.

(2) The Directorate responsible for biosafety shall be the Competent Authority.

(3) The Directorate shall consist of staff appointed by the Public Service Commission to carry out the functions of the Competent Authority and they shall be professionals in modern ~~biotechnology~~ Genetic Engineering and biosafety.

(4) The Directorate shall be headed by a director who shall act as the secretary to the National Biosafety Committee.

7. Functions of the Competent Authority.

(1) The functions of the Competent Authority are—

(a) to approve the research, 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, animal health and the environment during research, development, testing and use of a ~~GMO~~;

(d) to consider and ensure enforcement of necessary measures to avoid adverse effects on the environment, biological diversity, human health, animal health and on socio-economic conditions arising from ~~biotechnology~~ and its products;

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

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

(g) to liaise with the appropriate government agencies to prescribe the standards for regulating ~~biotechnology~~ and its products;

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

(i) to receive and screen completeness of ~~GMO~~ applications;

(j) to register all research institutions required to be registered under this Act;

(k) to keep a register of institutional biosafety committees;

(l) to prepare and issue certificates, permits and advance informed agreements;

(m) to inspect and monitor any person or activity authorised or approved under this Act.

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

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

(p) to build capacity in biosafety, and ~~biotechnology~~ Genetic Engineering research, development and innovation;

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

(r) 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 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.

9. Establishment of the Inter-Ministerial Policy Committee on ~~Biotechnology~~ Genetic Engineering and Biosafety.

(1) There is establish an Inter-Ministerial Policy Committee on ~~Biotechnology~~ Genetic Engineering and Biosafety.

(2) The Inter-Ministerial Policy Committee on ~~Biotechnology~~ Genetic Engineering and Biosafety shall consist of members set out in Schedule 2.

Consequential amendment to include Genetic Engineering.

President's Office Initiated and Approved

(3) The Prime Minister shall be the chairperson of the policy committee.

(4) The functions of the policy committee shall be—

(a) to provide strategic guidance on matters of ~~biotechnology~~ Genetic Engineering and biosafety; and

(b) to consider other matters of national interest in relation to ~~biotechnology~~ Genetic Engineering. and biosafety.

(5) The policy committee on ~~biotechnology~~ Genetic Engineering and biosafety shall conduct its business in accordance with Schedule 2.

(6) The Minister may, on the advise of the policy committee, amend Schedule 2.

National Biosafety Committee

Consequential amendment

10. Establishment of National Biosafety Committee.

(1) There is established a National Biosafety Committee.

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

(a) fourteen persons with at least ten years' experience from the following fields—

(i) breeding and genetics;

(ii) agronomy;

(iii) pathology;

(iv) molecular biology;

(v) food science;

(vi) toxicology;

(vii) ecology;

(viii)microbiology;

(ix) pharmacology;

(x) soil science;

(xi) industrial chemistry;

(xii) human medicinc;

(xiii) veterinary medicine; and

(xiv) consumer rights.

(b) a representative of the academia from any public University;

(c) an advocate nominated by the Uganda Law Society;

(d) a representative of the Uganda National Council for Science and Technology;

(e) a representative of farmers nominated by a nationally recognised farmers' umbrella association;

(f) a nominee from the Uganda National Bureau of Standards with experience and knowledge of standards of modern ~~biotechnology~~ and its products; and

(g) any other relevant ~~biotechnology~~ fields as may be recommended by the Competent Authority from time to time.

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

(4) The members of the Committee shall elect a chairperson from among members of the Committee appointed under subsection (2) (a).

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

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

(7) 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.

(8) Where a member of the Committee has resigned or been removed from office, the Minister shall appoint another person within sixty days.

(9) The chairperson of the Committee shall vacate his or her seat when he or she ceases to be a member of the Committee or where a vote of no confidence is passed against him or her by at least two thirds of the members of the Committee.

(10) The members of the Committee shall be paid allowances determined by the Minister after consultation with the Minister responsible for finance.

11. 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;

genetic Engineering.

(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;

genetic Engineering

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

12. Business of the Committee.

The National Biosafety Committee shall conduct its business in accordance with Schedule 3.

Institutional biosafety committees

Consequential

13. 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 biosafcty committcc cstablished 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—

(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); and

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

PART III—RESEARCH AND GENERAL RELEASE OF A GMO

14. 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.

15. 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;

(c) testing for full safety and risk assessment; and

(d) contained use.

16. Approval for each stage of research.
(1) A person shall before engaging in any stage of research obtain approval as follows—

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

(b) for testing—

(i) in the case of contained experiments or green house testing, from the Competent Authority through 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.

(c) in case of contained use, from the Competent Authority;

(d) in case of social environmental impact assessment, from the National Environment Management Authority.

(2) The Competent Authority shall, before the approval of any stage of research, ensure that an indigenous seed variety is preserved in the National Gene Bank.

17. 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 shall on conviction be liable to a fine not exceeding two hundred and forty currency points or imprisonment not exceeding ten 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

18. 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) A person who is not attached to any research institution, and wishes to engage in a GMO laboratory experiment shall before commencing research, notify any institutional biosafety committee of his or her choice.

(3) The notification shall be in Form 1 in Schedule 4 and shall be accompanied by the prescribed fee.

(4) The institutional biosafety committee shall within seven days after receipt of the notification under subsection (1) or (2), notify the Competent Authority of the application.

(5) The Competent Authority shall upon receipt of the notification, publish it in a newspaper of wide circulation requesting for public views.

(6) The public shall send their written views to the Competent Authority within fourteen days from the time of publication of the notice.

(7) The Competent Authority shall within thirty days after receipt of the notice under subsection (4) give directions to the institutional biosafety committee regarding the notification for research.

(8) The institutional biosafety committee shall within twenty one working days of receiving the directions, respond to the person who notified the institutional biosafety committee under subsection (1) or (2), informing the person whether to procced or not proceed with the experiment.

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

(10) Where the institutional biosafety committee does not respond to the person within the time specified in subsection (8), the person shall apply directly to the Competent Authority.

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

(1) An application for approval to conduct a contained experiment or green house testing of a GMO shall be made to the Competent Authority through the institutional biosafety committee in Form 1 in Schedule 4.

(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.

Provisions to be strengthen to prevent mixing indigenous seeds from GMO

(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 person shall apply to the Competent Authority.

20. 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 4.

(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.

= Amend to include isolation distance

21. 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 4.

(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;

Safety Periodic monitoring

(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, transportation and use of the GMO.

(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,* a newspaper of wide circulation 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 shall, within forty five days from the receipt of the notice or date of publication of the notice, make a presentation to the Competent Authority in respect of the application. .

22. 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 4 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—

(i) state the country of origin;

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

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

(iv) a report from a relevant government ministry, department or agency indicating that the product intended for import is necessary for use in Uganda; and that there is no alternative non-GMO material or product readily available;

(c) exportation, state the destination country.

23. 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 one hundred and twenty working days;

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