BIOSAFETY LEGISLATION IN UGANDA: A focus on Genetic Engineering Regulatory Bill, 2018 Presented at the 5th Annual National Biosafety Forum

By Harriet Ityang,

Ministry of Justice and Constitutional Affairs

BACKGROUND

- National Biotechnology and Biosafety Bill, 2012 was presented to the 10th Parliament on 4th October 2017
- Passed into an Act by the 10th Parliament and forwarded to H.E the President for Assent, President returned Bill to Parliament for reconsideration to review among others the title of the Bill, definition of genetic engineering and genetic engineered material, approval of the different stages of research, order to stop a GMO activity, labelling of GMO and its products as well as the Clause on liability for damages and offences and penalties;
- The 10th Parliament reconsidered the Bill and passed it as the Genetic Engineering Regulatory Act, 2018 and presented to the President for assent
- 22nd July, 2019 Bill returned to Parliament for reconsideration of clauses on benefit sharing, isolation measures and offences committed by a body corporate among others;
- Bill lapsed with the 10th Parliament before reconsideration and was never saved by the 11th Parliament.

Current status of GERA, 2018

- H.E on 15th May, 2022 directed that the Bill previously referred to Parliament be presented to Cabinet for fine tuning and to include the issue of use of gene therapy in human beings;
- GERA catered for agriculture and aspects of human and environmental safety but didn't cater for aspects of research and regulation of human genome manipulation as an aspect of human health;
- The scope of GERA would therefore need to be expanded to include the regulation of research and use of gene therapy for treatment of diseases in human beings.
- The AG has advised that Min of health, MSTI, MAAIF, UNCST and relevant stakeholders need to develop principles for a new legal framework to streamline the regulation of the use of biotechnology in all the relevant sectors.

GENETIC ENGINEERING REGULATORY ACT, 2018

- **An Act to regulate genetic engineering activities and facilitate safe development, transfer, application and utilisation of genetically engineered materials; to designate a National Focal Point, and establish a Competent Authority; to establish the Inter-Ministerial Policy Committee on Genetic Engineering; to establish a National Genetic Engineering Committee; to provide for the establishment of institutional genetic engineering committees; to provide mechanisms to regulate research, development and general release of genetically engineered materials and for related matters.**

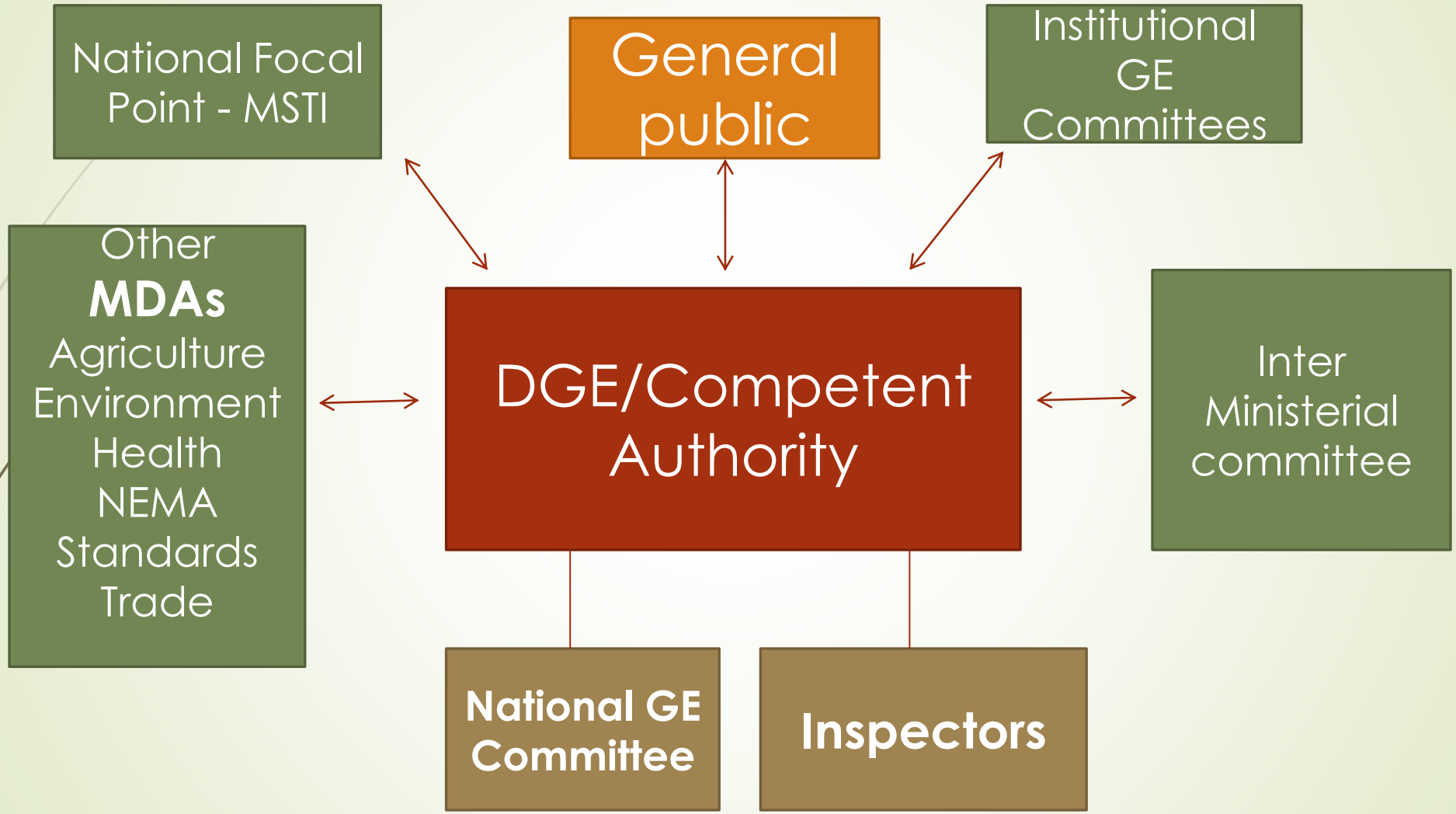
Application.

- This Act applies to research and general release of a GEM For the avoidance of doubt matters related to genetically engineered drugs shall be dealt with under the National Drug Policy and Authority Act.

The objectives of this Act are—

- to regulate genetic engineering and facilitate safe development, transfer, application and utilisation of genetically engineered materials;
- to facilitate and promote research, development and use of genetic engineering;
- to establish procedures for bio-ethical considerations in genetic engineering research;
- to strengthen consumer protection and public understanding of products and the benefits of genetic engineering;
- to facilitate safe use of genetic engineering to address national development challenges in food security, healthcare, biodiversity conservation and industrialisation;
- to build capacity in genetic engineering research, development and innovation;
- to promote technology transfer and benefit-sharing in the development and use of genetic engineering; and
- to build strong institutional relationships among genetic engineering stakeholders.

Institutional arrangements



Review/approval procedure

- Depends on nature of activity
  - Lab research, contained research, confined research, Full safety assessment, general release, import/export/ transit
- Review at institutional, and national levels
- NGEC main national body for biosafety matters – Under competent Authority = Department of GE
- All relevant government agencies to have input into specific applications
- All approvals/denials based on sound, scientifically acceptable risk and safety assessment

Stage / type of R&D	Approving Authority	Max. Review period (working days)	Remarks
Laboratory experiments	IGECs	30	IGEC and Competent Authority is notified
Contained testing	IGECs	28	To Competent Authority thru IGEC reviewed by NGEC
Confined field testing	Competent Authority (DGE)	90	To CA through the IGEC reviewed by NGEC
General release	Competent Authority (DGE)	270	To CA reviewed by NGEC; Other government agencies & public are consulted; Gazette
Import, Export, transit	Competent Authority (DGE)	28	Import permit from relevant government institution

Risk and safety assessment and management

- Bill emphasises safety in using biotechnology by providing for measures to be taken to minimise or avoid risk to human health and environment arising from actual or potential contact with a GEM.

- Also provides for every application for research or general release to contain an emergency plan complete with safety measures for unintentional release of a GEM.

Restoration and inspections

- Competent Authority may:
  - Stop an activity when human health or environment is threatened as a result of a GEM activity;
  - Stop unapproved activities;
  - Issue restoration orders in the event of damage to human health and the environment.
- Competent Authority may also:
  - Investigate any claims concerning GEM activities;
  - Conduct inspections as appropriate.

Regulations

- prescribing procedures for research involving genetically engineered materials;
- prescribing the procedures for general release of genetically engineered materials into the environment;
- for handling, transport, identification, labelling and packaging of genetically engineered materials;
- specifying the fees for applications and other services under this Act;
- specifying the safety levels and standards for safety of GEM and GEM products on the recommendation of the Uganda National Bureau of Standards;
- establishing procedures for bio-ethical considerations in genetic engineering research;
- prescribing penalties in respect of any contravention of the regulations; and
- for the better carrying into effect the provisions of this Act.

26. Labelling of a GEM.

A person involved in the research, development, general release, importation, exportation, transit or trade of a GEM shall—

- conspicuously label the GEM with the words "Contains Genetically Engineered Material"; and
- indicate the relevant characteristics and origin of the GEM.
  - A place where an activity involving a GEM is carried out shall be conspicuously labelled by the applicant or person to whom the approval was given to carry out a GEM activity, indicating the activity being carried out.
  - A person who contravenes this section commits an offence and shall on conviction be liable to a fine not exceeding one thousand currency points or imprisonment not exceeding six years or both the fine and imprisonment.

Liability and redress

- **35. Liability for damages.**
  - (1) A person who owns a patent in a GEM is strictly liable for any harm, injury or loss caused directly or indirectly by such a GEM to the community livelihood, indigenous knowledge systems or technologies, environment, biodiversity, ecosystem, species of flora and fauna, human or animal health.
  - (2) In this section, "a patent", means the exclusive right granted by a government to any person in respect of a GEM, to manufacture, use, or sell the GEM.

Offences and penalty

- A person who introduces a terminator seed, or a gene that is genetically engineered to make any offspring of a crop sterile, or unable to reproduce or uses genetic use restriction technology;

commits an offence and shall on conviction be liable to a fine not exceeding two thousand currency points or imprisonment not exceeding twenty years or both.

Definition of genetic engineering

"genetic engineering" means the application of;

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

"genetically engineered material" or "GEM" means an organism, or material produced through geneting engineering.

Thank you
for you kind attention