

## Key ministries to be involved in implementing this law include;

Finance, Planning and  
Economic Development  
/ UNCST

Agriculture, Animal  
Industry and  
Fisheries

Water and  
Environment

Health



**UGANDA BIOTECHNOLOGY & BIOSAFETY CONSORTIUM**

# The National Biotechnology and Biosafety Bill, 2012: Simplified Version

(Bill No 18 of 2012, Republic of Uganda)

## Purpose of the Bill

- The Bill is for an Act to ensure the safe development and use of modern biotechnology;
- To provide mechanisms to regulate research, development and use of genetically modified organisms.

## Key terms used in the Bill

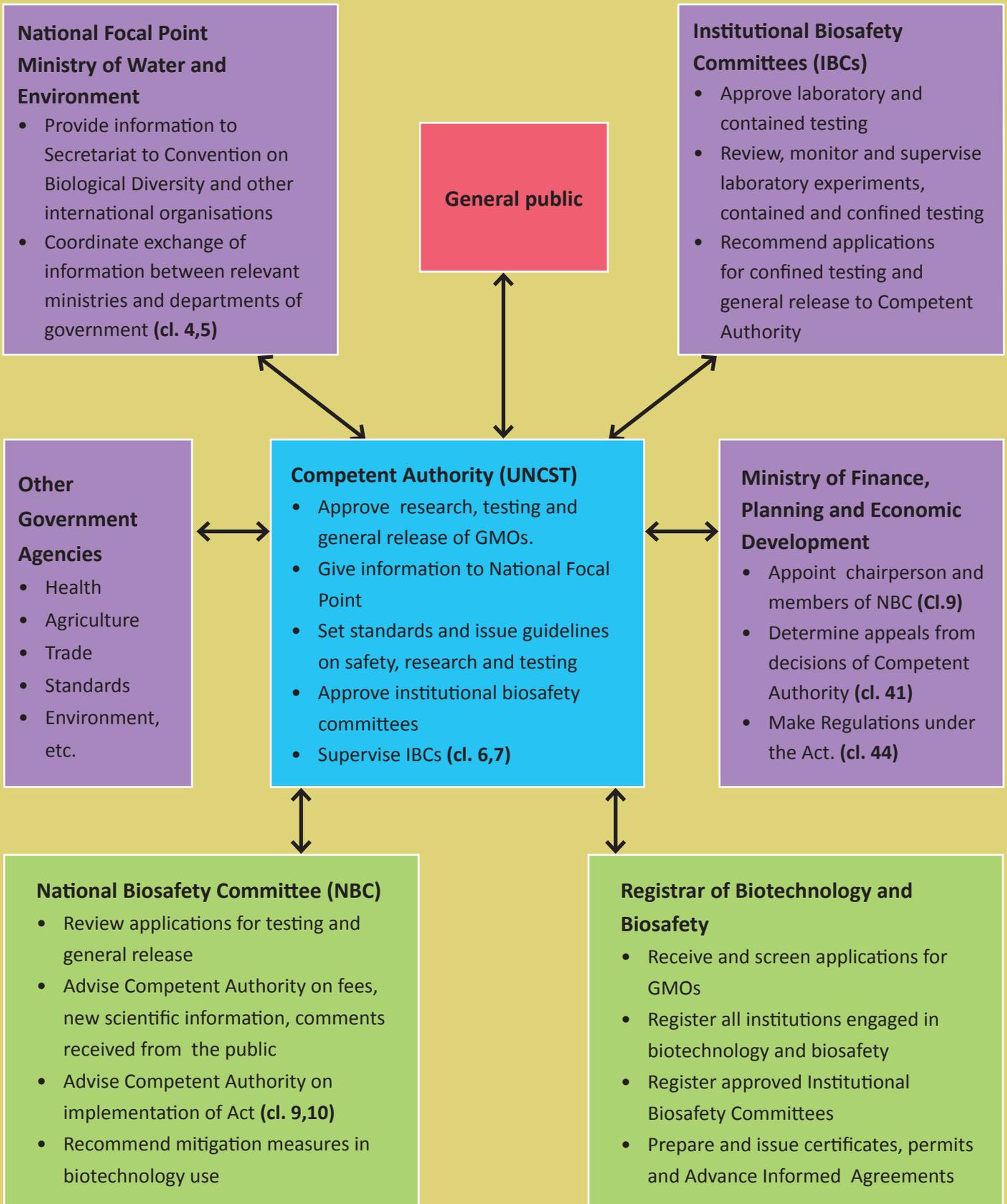
The Bill defines the following:

- (a) "biosafety" means the safe development, transfer, application and utilisation of biotechnology and its products
- (b) "biotechnology" means 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
- (c) "genetically modified organism or GMO" (also called transgenic or product of modern biotechnology) means an organism, consisting of any of the genes or other genetic material that have either been:-
  - modified by means of modern biotechnologies; or
  - inherited from genes or other genetic material which were so modified.

## Objectives of the Bill (clause 2)

- ❖ *to ensure the safe development and use of modern biotechnology for national development;*
- ❖ *to establish procedures application and approval to use modern biotechnology at various levels including research and general release;*
- ❖ *to strengthen consumer protection and public understanding of products and the benefits of biotechnology;*
- ❖ *to build human and institutional capacity to promote safe generation and use of modern biotechnology products.*

## Institutional framework; Roles in biosafety management in Uganda



## Approval of research and development of biotechnology

Stage / type of R&D	Approving Authority	Max. Review period (working days)	Remarks
Laboratory experiments	IBCs	21	Competent Authority is notified
Contained testing	IBCs	28	Competent Authority is notified
Confined field trial	Competent Authority (UNCST)	90	IBC recommends
General release	Competent Authority (UNCST)	270	IBC recommends; Other government agencies & public are consulted; Gazette
Import, Export, transit	Competent Authority (UNCST)	28	Fulfill Cartagena PB W/A

- UNCST: Uganda National Council for Science and Technology
- All approval by competent authority based on advise from NBC

## Risk and safety assessment

- All GMO research and development activity approvals are based on thorough risk and safety assessment
- The risk and safety assessment shall be carried out in accordance with international best practices and guidelines
- All applications must contain emergency plans to manage unintentional environmental releases

## Restoring damage caused by a GMO

In the event that an activity involving a GMO causes damage to human health or the environment, the Competent Authority may issue a restoration order to the person causing the damage. Such orders can also be issued for

- ✓ Activities relating to a GMO without or beyond the approval of the Competent Authority;
- ✓ In cases of damage caused by the unintentional release of a GMO attributable to a person;
- ✓ Where the Competent Authority has issued an order to the person to stop research or general release of a GMO;
- ✓ In any other cases where the activity of a person has caused damage. Cl.31

## Offences and penalties

Offence	Penalty
Research or making general release of a GMO without approval	Max. 120 currency points or max. 5 years or both
Failing to disclose any information as required by this Act	Max. 48 currency points or max. 24 months or both
Furnishing false information	Max. 48 currency points or max. 24 months or both
Releasing or using any confidential information for any purpose not authorized under the Act	Max. 48 currency points or max. 24 months or both
Using a GMO in a manner inconsistent with the approval granted under the Act	Max. 24 currency points or max. 12 months or both
Using a GMO to deliberately harm or injure the environment or human health	Max. 240 currency points or max. 10 years or both
Obstructing the Competent Authority or an officer of the Competent Authority from the performance of their duties under the Act	Max. 24 currency points or max. 12 months or both
Neglecting, refusing or failing to take emergency safety measures in case of unintentional release of a GMO	Max. 120 currency points or max. 5 years or both

<sup>a</sup>One currency point is currently equivalent to UGX 20,000 and is set by the government.

## Regulations

The Minister responsible for science and technology may, after consultation with the Competent Authority, make regulations for the purpose of carrying into effect the provisions of this Act. Some of these regulations will include:

- ✓ Procedures for conducting research
- ✓ Procedures for general release
- ✓ Procedures for handling, transport, labeling, packaging
- ✓ Bioethical considerations
- ✓ Penalties
- ✓ Any other regulation for effective implementation of the proposed Act.

## Schedules

1. Currency point
2. NBC conduct of business
3. Forms
  - a. Lab research
  - b. Contained testing
  - c. Confined testing
  - d. General release
  - e. Import/export, transit
4. Risk and safety assessment procedure



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 c/o Uganda National Council for Science and Technology  
 Plot 6, Kimera Road, Ntinda P. O. Box 6884, Kampala- Uganda  
 Tel: +256 714110088 +256 772585211 Email: ubbconsortium@gmail.com