Biosafety Concerns and Regulatory Framework in Kenya

Kenya’s capacity to regulate Biotechnology Activities and Products

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Outline

● Institutional Capacity
● Laboratory capacity
● Regional Capacity
● Capacity in Universities
● Bio-Containment and Confinement capacity
● Legal and administrative capacity
● Institutional Collaboration
Institutional Capacity

KEPHIS

- Release of plant varieties. GM Varieties are not exceptional
- Participation in Institutional Biosafety committees.
- Participation in decision making at the Board of the National Biosafety Authority
- Competent staff: MSc, PhD

National Biosafety Authority

- Competent staff: MSc, PhD
- Coordination structure for regulatory agencies in place
OMESA Referral Laboratory at the Plant Quarantine and Biosecurity Station is fitted with modern equipment and capacity for:
- Real time PCR
- Conventional PCR
- ELISA
- Rapid Strips
World Class laboratory at KEPHIS Headquarters housing:

- Molecular laboratory (Realtime PCR, Conventional PCR, ELISA, Rapid Kits)
- Plant Health Laboratory
- Food microbiology laboratory
- Analytical Chemistry Laboratory
Laboratory testing Equipment

- ELISA Reader
- Real time PCR
- -80 Freezer
- Real time PCR Curve
Regional Capacity at BeCA - ILRI

Bioinformatics, DNA sequencing, Genotyping and Oligonucleotide synthesis
Modern biosciences training laboratory
University of Nairobi and Kenyatta University

Biotechnology Centers available
Cartagena Protocol Based Bio-Containment facility at KARI Biotechnology Centre
Cartagena Protocol Based confined Field Facilities in KARI Stations

• Confined Field Trials (CFT) conducted for a number of GM crops since 1991 when the first CFT (sweet potato) was initiated.

• Experience has been gained by researchers & regulators.

• Now there is a specific law and regulations as well as Standard Operating Procedures
  • Isolation maintained
  • Protection from animals, man, environment during trials
Legal and administrative capacity

International
● Codex Alimentarius (FAO/WHO): Principles of risk analysis and guidelines for food safety assessment – NBA could use the principles for Food safety assessment
● Cartagena Protocol on Biosafety (CBD/UNEP): Safe transfer, handling, transboundary movement – KEPHIS participates in implementation
● International Plant Protection Convention (FAO): Standards for risk analysis – KEPHIS is a signatory to this Convention

National
● Kenya Standards on Food safety for Modern Biotechnology
● Effective border control and monitoring system – KEPHIS has inspectors at all major port of entry.
● The Kenya Standing Technical Committee on Imports and Export.
● A National Policy on Biotechnology approved by Cabinet in 2006
● The Biosafety Act was gazetted in February 2009 – NBA implements the Act together with regulatory agencies
● Regulations of the Biosafety Act
Institutional Collaboration

- The capacities in the country are in different government and regional agencies.
- It is therefore critical that the NBA signs MoUs with relevant agencies to utilise the available capacity.