

The Recent Meeting and policy development in Uganda's policy on biosafety (biosecurity)

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By

**Maxwell Otim Onapa
Uganda National Council for Science and Technology**



Uganda National Council For Science and Technology
(Established by Act of Parliament of the Republic of Uganda)

The Recent Meeting

- What was it about?
- What transpired?
- Uganda's BT and BS policy: How far does it go?



Theme: Promotion of Biosafety and Biosecurity within the Life Sciences

Objectives:

- To inform African Scientists and policy makers on issues related to the inadvertent or deliberate spread of disease stemming from life science research
- To provide a platform that brings international experts on biosafety and biosecurity in direct contact with local scientists, academy members and policy makers in order to:
 - Initiate dialogue regarding policy responses and practical institutional measures stemming from presentations by experts



Issues Discussed

- Biosafety and biotechnology in Uganda
- Biosecurity
- Building a coalition
 - Improving oversight
- From the Global to a local perspective: setting priorities
- Roundtable discussions
 - Biosafety/biosecurity Scientists and policymakers roundtable



Issues noted

- Biosafety and Biosecurity are important to African Nations
- Combating emerging infectious diseases and the threat of bioterrorism require collective actions
- Biosecurity is not well understood in Africa and the terms biosafety and biosecurity are often confused
- There are multiple definitions of biosafety and biosecurity – one must be very clear which aspect of biosecurity is being discussed
- Biorisks – public health, biosafety and biosecurity
- Primary risk comes from nature and not laboratory but some infectious agents can spread from the laboratory and endanger the public



Issues that emerged

- Protecting against the misuse of the life sciences requires a web of deterrence
- Responsibility for biosafety and biosecurity lie at multiple levels
- Achieving biosecurity involves risk assessment, policy development, and adherence to biosafety and biosecurity protocols
- Approaches to Achieving biosecurity
- Regulation most common for biosecurity
- Various organizations involved in biosafety and biosecurity



Issues that emerged

- Scientists and policy makers should become engaged in promoting biosafety and biosecurity
- Education and awareness raising are critical
- Dual use research issues
- Biosecurity is necessary for Ag-GMO foods is needed for consumer protection – **Cartegena Protocol** for biosafety provides framework
- Capacity building is needed for public health
- Systems are needed to mitigate risk
- Various organizations are developing protocols for managing dual use research, biosafety, and biosecurity



Uganda National Biosafety and Biotechnology policy

Focus: Setting up national biosafety system to manage modern gene-based biotech – GM Technology

Premise of Biosafety: International Agreement

- **Cartegena protocol on Biosafety 2000** – negotiated after a realization that biosafety cannot be achieved without coordinated approach between countries.
 - To ensure adequate level of protection in the field of safe transfer, handling and use of LMO's taking into account risks to human health, and specifically focusing on transboundary movements
- **Codex Alimentarius**
 - Develop guidelines on food and feed derived from GE products and sets international standards on food safety and control (FAO/WHO 2003)
 - **African model Law on safety in biotechnology**



National Biosafety and Biotechnology policy

Major objectives of National Biosafety System

- Establish a system where a country can benefit from modern biotech while avoiding possible risks
- Ensure that the research, development, handling, transboundary movement, transit, use, release and management of GE products are undertaken in a manner that prevents risks to human health, biological diversity and the environment.



Development of the Uganda Biosafety system

- 1993 Uganda ratified the Convention on Biological Diversity and Min of Water Land & Environ became the **focal point**
- 1996 A National Biosafety Committee (NBC) was established, UNCST became the **competent authority** for biosafety in biotechnology
- National Biosafety Guidelines were drafted and approved by the NBC
- ALVAC HIV trial application is reviewed by the **NBC**
- UNEP-GEF launched a project to assist Uganda develop its national biosafety framework



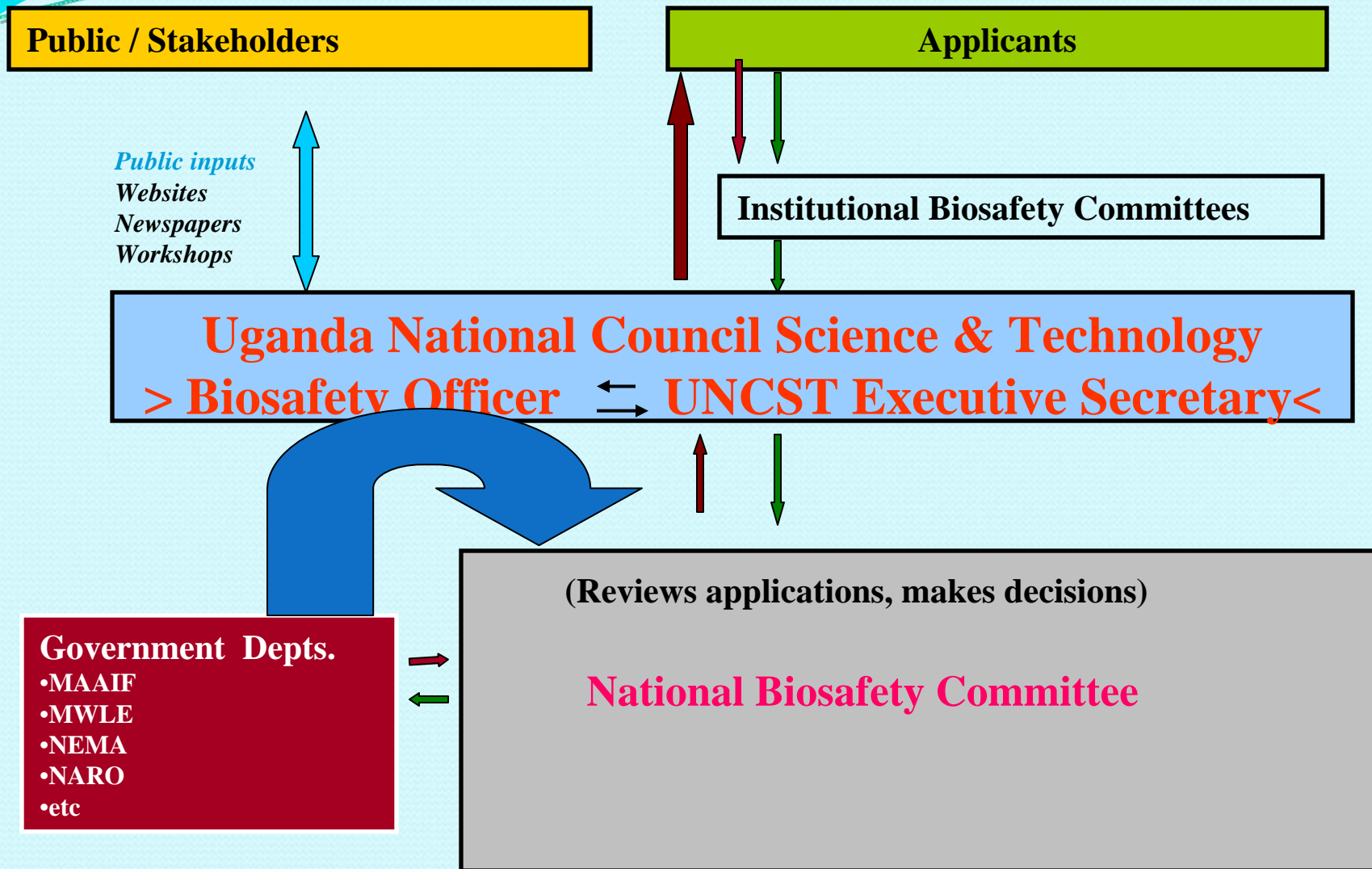
Development.....

- 2000 Cartagena Protocol on Biosafety signed
- 2001 Cartagena Protocol on Biosafety ratified
- 2002 Uganda receives a grant by UNEP-GEF to implement its National Biosafety Framework.
- 2003 Government develops a National position on Biotechnology
- 2008 Biotechnology and Biosafety Policy approved

Discussions on biosafety bill accomplished



Biotechnology/Biosafety Governance in Uganda



Courtesy: Charles Mugoya, ASARECA



Implementing international obligations in Biotechnology and Biosafety

1. Convention for Biological Diversity

- Min of Water is the focal point for the CBD
- Made input into all COP negotiations since 1992

2. Cartagena Biosafety Protocol

- **Min of water** is the focal point
- Hosts the national BCH
- **UNCST** is a competent authority



Components of the National Biosafety system

- National policies
- **Legal regime**
- **Administrative and Decision Mechanisms**
- Monitoring Mechanisms
- Mechanisms for public awareness, Education and Participation
- Science Knowledge base, skills and Capacity



Legal regime

- A draft bill developed for presentation in parliament
- Key objectives of the legal system
 - Facilitate responsible application
 - Effective level of protection
 - Establish administrative structures



Administrative and Decision Mechanisms

- Cartagena protocol model system
 - National Focal Point
 - Competent Authority
 - Regulatory Agencies

Function of National Focal Point

- To provide coordinated communication on behalf of all relevant ministries, agencies, and departments of Uganda on matters of Biosafety to govts, international organizations, including the secretariat to Biosafety protocol

Functions of the Regulatory Agencies

- Provide expert advise
- Issues permits
- Inspect and monitor compliance



Administrative and Decision Mechanisms

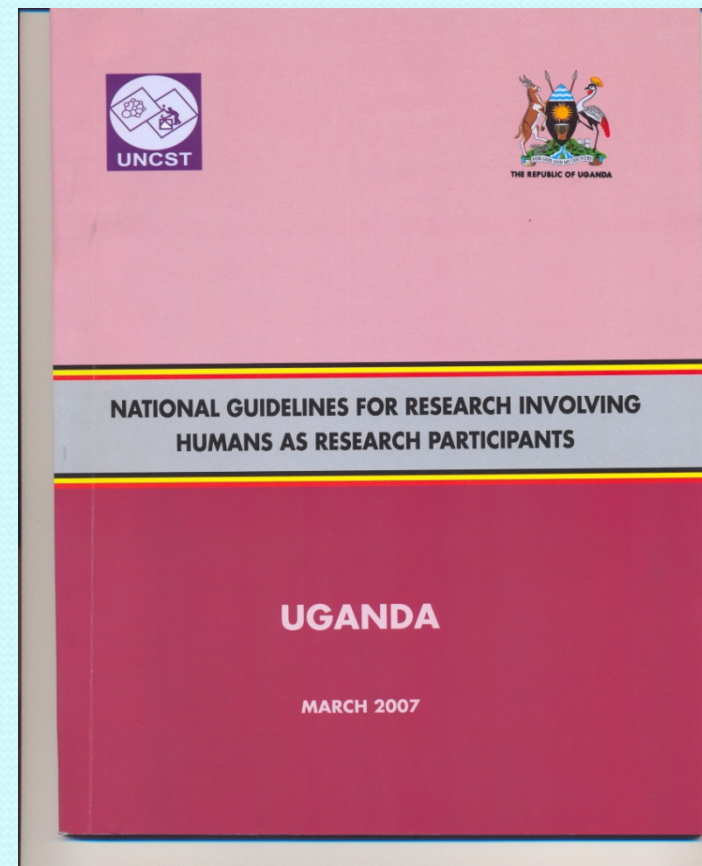
Functions of Competent Authority – UNCST

- Prescribe criteria, standards, guidelines and regulations in accordance with govt policy/law
- Establish and empower NBC
- Implement decisions of the NBC
- Assist relevant institutions to establish IBCs
- Establish database on GMOs
- Promote public awareness and education on Biosafety
- Received applications and grant approval relating to making, import or use of GMO
- Identify national requirements for manpower development and capacity building in biosafety



UNCST – The Competent Authority

- Policy development
- Guide and coordinate R&D
 - Research registration and clearance
 - Research monitoring
 - Uganda Society for Health Scientists – Bioethics working group



Conclusion

- BT and BS policy in place
- **Biosecurity not fully addressed**
- Other actors' positions equally unclear
 - Makerere University – FVM proposing a training initiative
 - Proposes Bach. of biosecurity and Biosafety Engineering

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FIFTY-EIGHTH WORLD HEALTH ASSEMBLY International Health Regulations

PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 23 Health measures on arrival and departure

- **Sect 5. Any medical examination, medical procedure, vaccination or other prophylaxis** which involves a risk of disease transmission shall only be performed on, or administered to, a traveler in accordance with **established national or international safety guidelines** and standards so as to minimize such a risk.



Thank you for your kind
attention



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