



# **THE UGANDAN EXPERIENCE IN REGULATING BIOTECHNOLOGY SINCE 1996: Lessons and Opportunities Going Forward**

By:

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# Background

- UNCST was established by an Act of Parliament, the UNCST Act, of 1990
- The Act gives it a mandate to:
  - Clear all scientific research and development activities in the country;
  - Advise government on all aspects of Science and Technology.
- Early 1990s the UNCST realized that modern Biotechnology - becoming increasingly important in Agriculture, Medicine, Industry, etc;
- Need for Uganda to also incorporate modern biotechnology in Uganda's R & D agenda

# Background (cont'd)

- UNCST called a meeting in April 1994; of key stakeholders in the relevant fields; targeting both experts from government MDAs, Research Institutions, Academia, as well as Private Sector;
- The experts appreciated the growing importance of modern biotechnology, but also the controversy and fears the technology had generated worldwide regarding its safety;
- Identified the need for national capacity building in modern biotechnology, if the technology was to be introduced safely and to benefit Ugandans;
- Resolved that Uganda needed to develop Guidelines on Biosafety;

# Background (cont'd)

- Recommended that a Committee be formed to oversee the formulation of the Guidelines and Regulations governing Biotechnology Research, Development and Applications;
- UNCST appointed the members of the (multi-disciplinary) Committee, known as the National Biosafety Committee (NBC) in November 1995 and it was launched in March 1996;
- To date, the Committee has considered, approved and overseen close to 20 applications for CFTs and other Trials for Research and generation of safety-related data;
- It has also overseen the development of various Biosafety assessment Standards, Guidelines and tools, and made inputs into the Draft Biosafety Bill

# **Some of the Handled Activities by NBC to-date**

## **Vaccines**

- In 1996, proposal to try a genetically engineered HIV-1 vaccine (ALVAC Vcp 205) in Uganda--the first in Africa;
- Subolesin-based Anti-tick Vaccine in Cattle (2022);

## **Research and Diagnostics Laboratories**

- Mweya Peninsula- UWA- Wildlife pathogens
- Fort Portal Regional Referral Hospital
- CoVAB, Makerere University – livestock
- NaLIRRI /NARO –Nakyesasa
- UVRI - Entebbe

# Some of the Handled Activities (cont'd)

<b>Commodity</b>	<b>Areas under Research &amp; Development</b>
<b>Banana</b>	<b>Black Sigatoka disease resistance, Fortification with Pro-vitamin A and Iron; bacterial wilt resistance, Nematode and Banana weevil resistance</b>
<b>Maize</b>	<b>Drought tolerance; Stem borer pest resistance</b>
<b>Cassava</b>	<b>Cassava Brown streak disease resistance; Cassava mosaic resistance; Whitefly resistance</b>
<b>Rice</b>	<b>Nutrient use efficiency</b>
<b>Potato</b>	<b>Potato Blight Resistance</b>
<b>Cotton</b>	<b>Pest resistance and Roundup herbicide tolerance</b>
<b>Sweet potato</b>	<b>Sweet Potato Virus Disease resistance</b>
<b>Soybean</b>	<b>Glyphosate Herbicide tolerance</b>
<b>Livestock</b>	<b>Anti-tick Vaccine development/ testing</b>

# Procedure in handling applications

- Application received and checked for completeness at the UNCST/NBC Secretariat;
- Application is tabled before the Full NBC meeting;
- Application is referred to a sub-committee of the NBC (3-5 members with expertise in the subject matter);
- Sub-committee reports back to next NBC meeting and any issues raised, referred to Applicant;
- Applicant invited (if necessary) to present to NBC;
- Application approved (with or without conditions) or rejected.

# Developments at International Level that informed the Regulatory Process

- CBD (1992), ratified by Uganda, 1993: –
- Article 8 (g): Parties to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from Biotechnology, which are likely to have adverse environmental impacts, that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health”



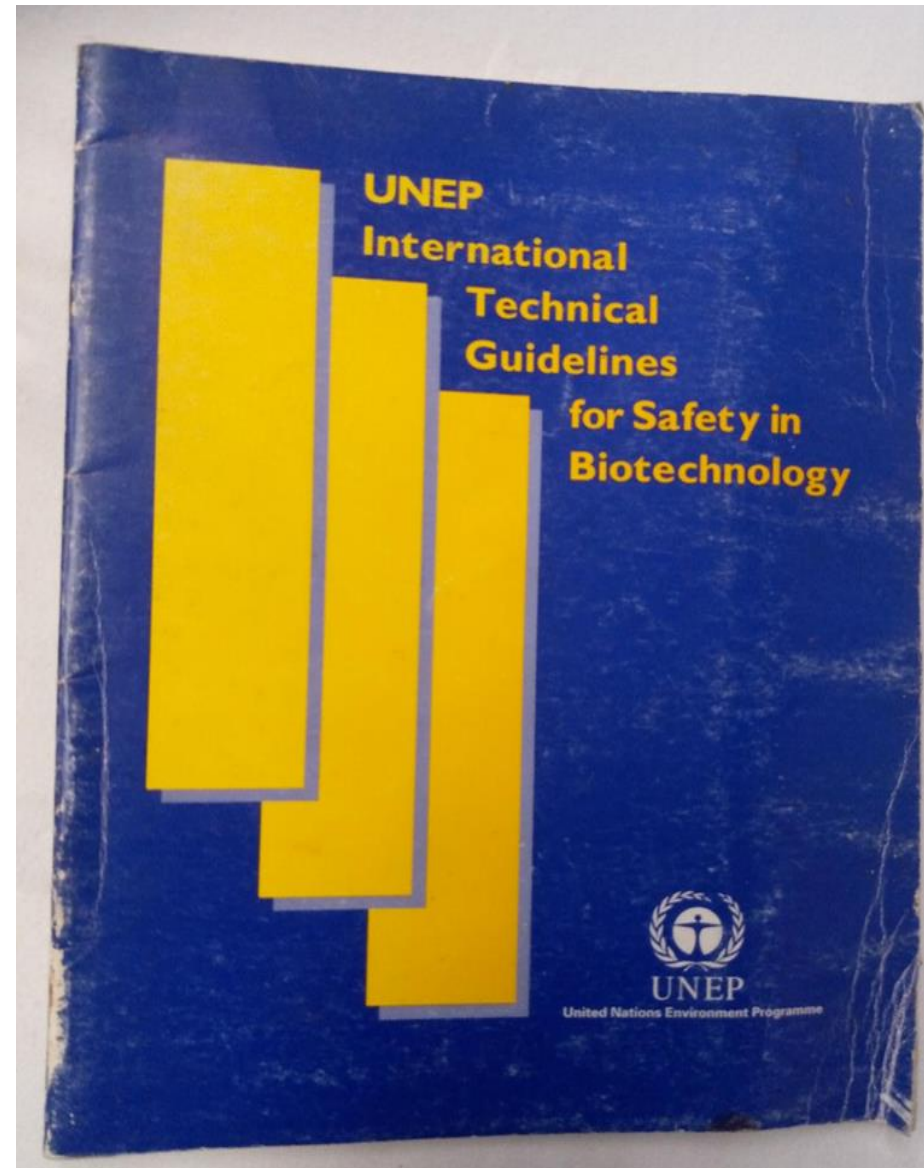
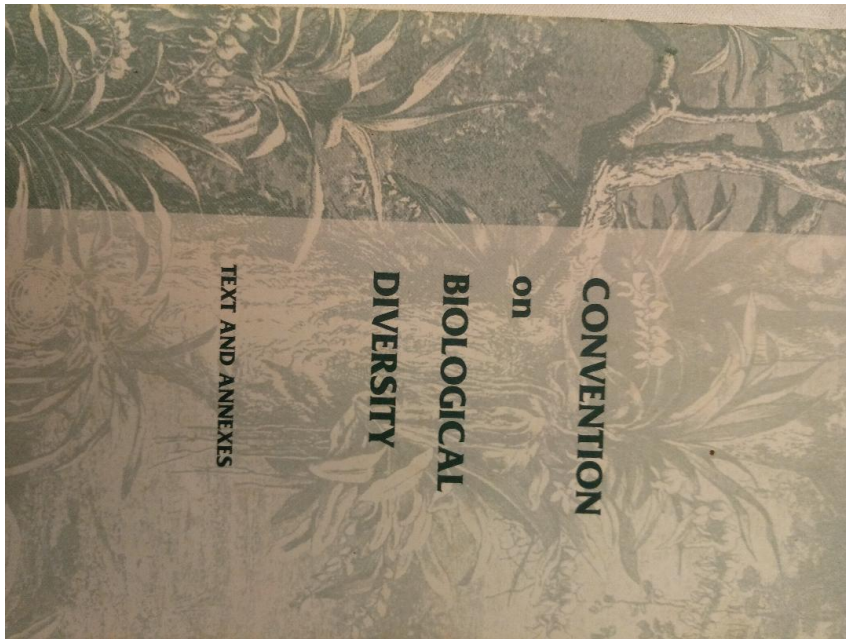
# Developments at International level (cont'd)

- Article 19 (3): Parties shall consider the need for a Protocol ..... AIA, in the field of safe transfer, handling and use of LMOs..... The result, the Cartagena Protocol on Biosafety (Uganda ratified it, 2001).
- Requires Parties to take necessary legal, administrative and other measures to implement their obligations under the Protocol;
- Puts in place decision-making and administrative procedures, RA and RM, Public Participation, and Risk Assessment Guidance;
- Capacity-building Initiatives, put in place and encouraged (UNEP/GEF Project on National Biosafety Frameworks – Uganda benefitted in late 1990s)

# Developments at International level (cont'd)

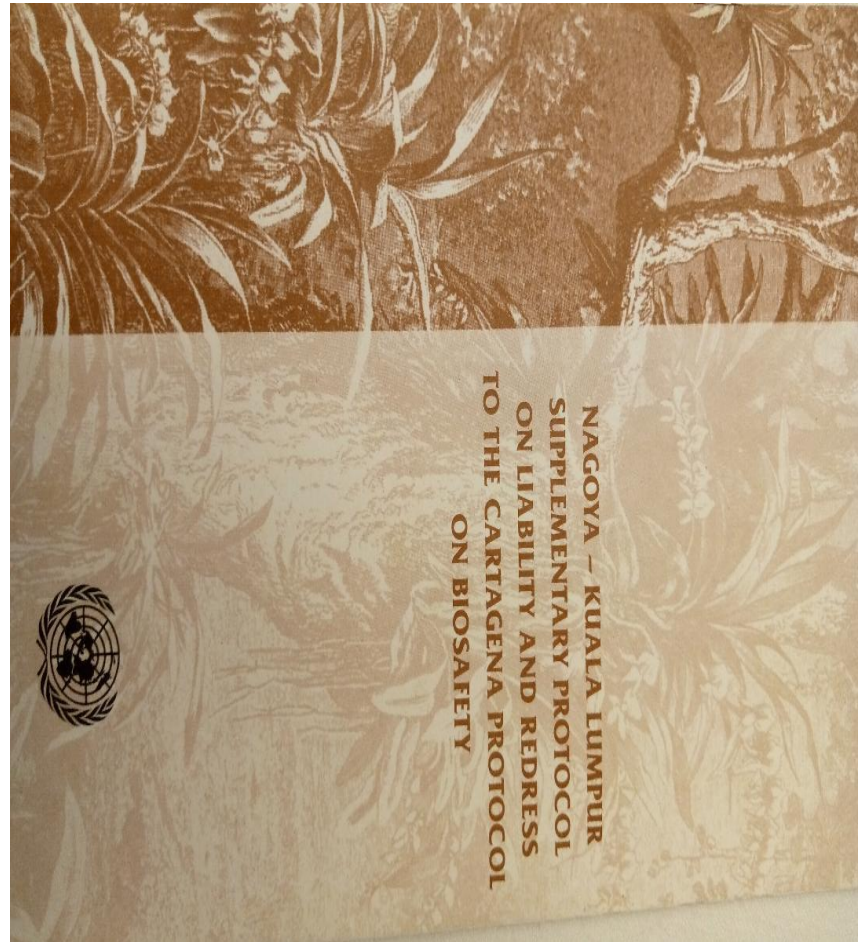
- UNEP (1995) – International Technical Guidelines on Safety in Biotechnology (Countries that needed to make laws could use);
- OAU, now African Union developed an Model Law on Safety in Biotechnology (2002) – to help countries in drafting national laws;
- Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol (ratified by Uganda, June 2014);
- **The developments at international level kept informing and improving the National processes**

# Some Products from global processes

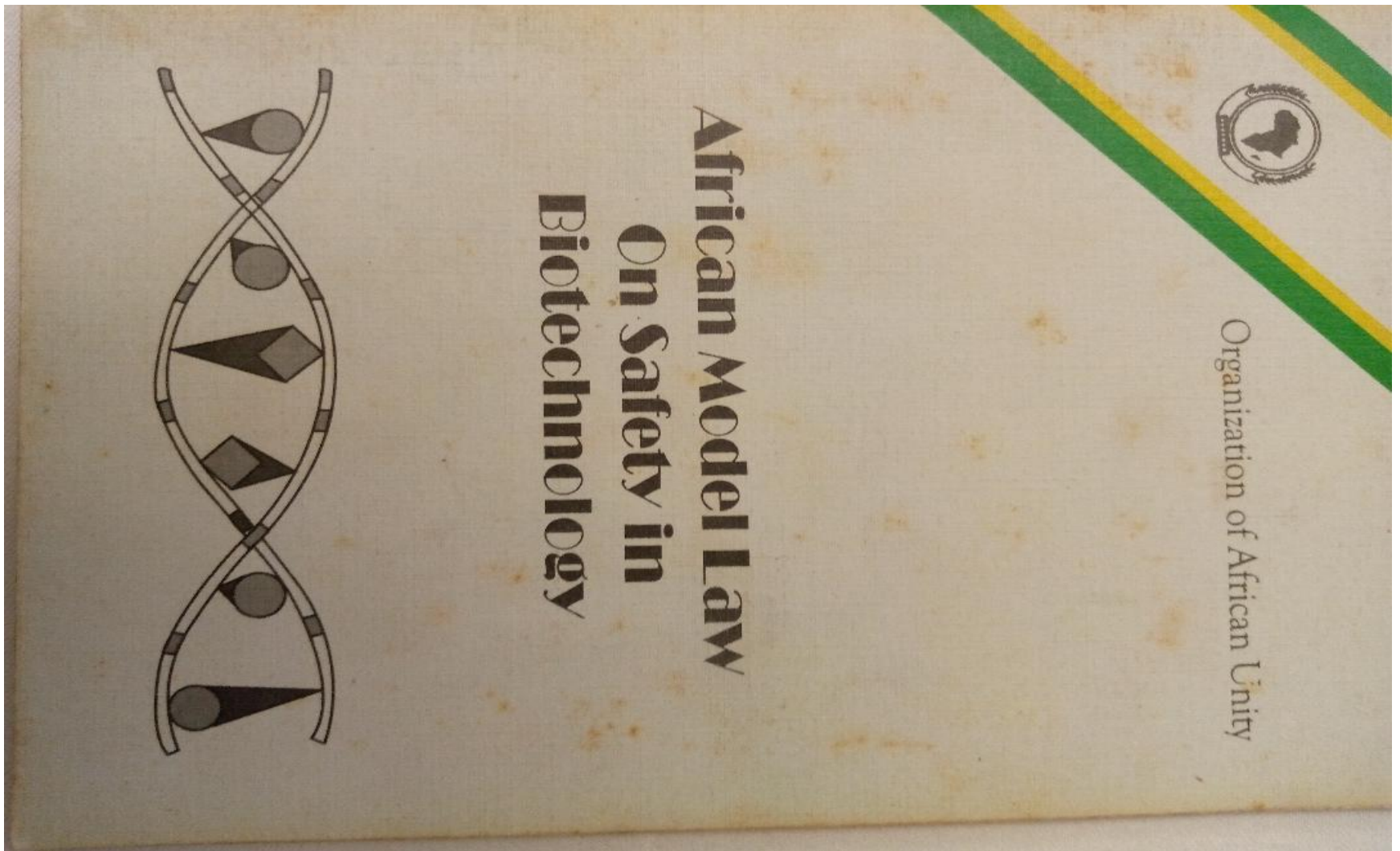




# Some Products from global processes



# Some Products from global processes



# **Some of the Standards, Tools and Guidelines developed by UNCST/NBC (and partners)**

- NBC SOPs (1<sup>st</sup> Draft 2005), published in 2012;
- Biosafety Inspection Manual for Field Experiments Involving G E Crops, 2007;
- National Guidelines for Containment: for Regulation of Research with GMOs and Microbes, 2007;
- National Biotechnology and Biosafety Policy (2008);
- Guidelines for interpretation of data for safety assessment of foods derived from recombinant DNA plants published by UNBS, 2010;
- National Guidelines for Field Trials of GE Plants, 2011;
- SOPs for Institutional Biosafety Committees in Uganda (2021)

# **Some of the Standards, Tools and Guidelines developed by UNCST/NBC (and partners)**

## **Awaiting Official Approval**

- Biosafety Inspection Manual for CFTs involving G E Crops (2021);
- Standard Operating Procedures for Conducting Contained and Confined use Research involving G M Animals and Arthropods (2020);
- Guidelines for Review and Risk Assessment of New Breeding Techniques, for Uganda (2020);
- SOPs for Import and/or Handling of Food and Feed containing G M Ingredients (2020);

# **Some of the Standards, Tools (cont'd)**

## **Awaiting Approval (Developed in Collaboration with NEMA)**

- National Guidelines for the Protection of the Environment and Management of Risks to Human Health, from the Development, Access and Use; and Transfer of GMOs (2021);
- National Guidelines for Liability and Redress for Damage or Harm as a Result of GMOs (2021).



# Challenges and Opportunities

## Challenges

- Low staffing levels at the UNCST for Biosafety;
- High Staff Turnover at the Secretariat;
- Limited Financial Resources;
- NBC Membership keeps changing (good or Bad?);
- Slow legislative process – no law

## Opportunities

- Better capacity built over time in the country;
- Conducive Political environment for the STI;
- International collaborators (info, Tech transfer)

# Lessons Learnt

- IPR issues getting understood across the board: agree (in writing) with your collaborators on IPR from the start;
- Best technologies, are best developed, and funded nationally, for solving national problems;
- Biosafety is cross-cutting: no single Institution is self- sufficient; Institutional/ Sectoral collaboration will always be necessary;
- Technology is developing faster than regulation;
- Keep ears on the ground for developments regionally and globally.

# Inception, Present and Future

- We started kind of groping in the dark;
- We have reached where we have national Capacity (more still needed), with products ready for release (if the law was in place);
- We need to finalize the law (taking into account concerns raised two years ago, new and upcoming techniques) and complete the regulatory framework;
- We need (**Nationally generated**) funds to tailor new products that feed into Industrial value chains to leap us into the desired future!