

Gene drive regulation and the challenges to be addressed with social research

Where are we?

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A little bit about me.....

- ❑ **Independent Consultant** – Science and Technology, Agriculture and Environment, Biotechnology, Biosafety Biopolicy and Biosecurity.
- ❑ **Associate Executive Secretary (2000-2005)** - Uganda National Council for Science and Technology
- ❑ **Programme Manager (2005-2015)** – ASARECA, Agro-biodiversity and Biotechnology Programme
- ❑ **Regional Coordinator(1999-2005)** – East African Network for Biotechnology, Biosafety and Biopolicy Development (BIOEARN)
- ❑ **ICIPE-PESTNET Program Coordinator (1992-1996)** - Country Manager, Zambia
- ❑ **Member NBC** – 1996-to date
- ❑ **Chairman NBC** - 2016- to date
- ❑ **Steering Committee Member** - African Union (AU) Biosafety Forum
- ❑ **Uganda Delegate** - COP-MOP meetings to the CBD

Presentation outline

- ❑ Uganda's National Biosafety Framework – for Gene Drive Technology
 1. **Policies and Legal Frameworks;**
 - a. National policies and Strategies
 - b. National Laws and Regulations
 - c. International Conventions
 - d. African Regional Frameworks
 2. **Administrative System;**
 3. **Risk Assessment and Risk Management System;**
 4. **Public Information and Participation System;**
 5. **Inspections and Monitoring System.**
- ❑ **Challenges** - that need to be addressed by Social Science research
- ❑ **Conclusions and recommendations**

The Place for regulation in Global, Regional and National affairs

Regulation occurs at different levels:

- ❑ **International** – International Conventions, Treaties and Agreements
- ❑ **National** – Through Government Ministries, Agencies
- ❑ **Regional** – for example at African Union, East African Community, COMESA, IGAD etc
- ❑ **Local Government/Municipal Authorities** – through bylaws
- ❑ **Institutional** – Institutional mandates, IBCs and Committees

Scope of regulatory requirements involving Gene Drive organisms

- General Biosafety aspects -
- Research Ethics aspects -
- Human Subject Research Requirements -
- Environmental Health aspects -
- Transportation Regulations aspects -
- Quarantine Regulations -

1a. National Policies and Strategies

- National Science, Technology and Innovation Policy
- National Biosafety Policy
- National Health Policy
- National Laboratory Health Policy
- National Health Security Policy
- National Wildlife Policy
- Occupational Health Policy
- One Health Strategy and Action Plan
- Local government/Decentralization Policy
- National Environment Policy and Action Plan
- National Biodiversity Strategy and Action Plan
- Others

1b. National Laws and Regulations relating to Gene Drive

- Constitution of Uganda, 1995
- Uganda National Council for Science and Technology Act 1990
- Public Health Act, 2015
- National Environment Act, 2019
- Uganda National Health Research Act
- Draft Genetic Engineering Regulatory Act 2019
- Few more others

1c. International Conventions

□ Convention for Biological Diversity (CBD)

– An important International Treaty –setting the regulatory pace

- a) Article 3: Principle - Sovereign right to exploit own resources without damage to own environment or that of other states
- b) Article 4 - Jurisdictional scope
- c) Article 5 - Cooperation between states
- d) Article 8 - In-situ conservation
- e) Article 14 - Impact Assessment and Minimizing adverse impacts
- f) Article 17- Exchange of Information

□ Cartagena Protocol on Biosafety (CPB)

– Most significant International Treaty that influences regulation of gene drive mosquitoes

– Affirms the precautionary approach

- a) Article 4 - Transboundary movement, transit, handling and use
- a) Article 6 - Transit and contained use
- b) Article 8 - Notification procedures
- c) Article 10 - Decision making procedures
- d) Article 14 – Concerns bilateral, regional and multilateral agreements and arrangements
- e) Article 17- Unintentional transboundary movements and emergency measures
- f) Article 19 – Assignment of Competent Authorities

1c. International Conventions

- ❑ **WHO-TDR Technical Consultations on GM Vectors**
 - *Has defined requirements for testing and implementation of GM vectors*
- ❑ **International Plant Protection Convention (IPPC) Guidelines for the Export, Shipment, Import and Release of Biological Agents and other Beneficial Organisms**
 - *Has set international standards for risk management of biological control agents capable of self replication*
- ❑ **Daegu Protocol on new technologies for pest and disease control**
 - *Has established guidance on regulation of biotechnologies related to crop pests and human disease vectors*
- ❑ **WHO-TDR MosqGuide project**
 - *Has developed best practices for decision making in the use of GM mosquitoes in disease endemic countries*
- ❑ **FNIH Working Group on contained Field Trials of vector mosquitoes engineered to contain a gene drive**
 - *Has developed guidance for the conduct of Phase 2 contained field trials for GM mosquitoes with self limiting or self sustaining gene drive.*
- ❑ **WHO-TDR and FNIH**
 - *Has developed guidance framework for the evaluation of GM mosquitoes including quality standards for assessing safety and efficacy considerations*

1c. International Conventions

- ❑ **AHTEG on Risk assessment and Risk management under the Cartagena Protocol**
 - *Has developed a road map and guidance on RA and RM of GMOs to supplement Annex iii of the Cartagena Protocol with a special section on living modified mosquitoes.*
- ❑ **Environmental Agency of Austria and the International Atomic Energy Agency (IAEA)**
 - *Have defined environmental risk assessment criteria for GM insects in the EU.*
- ❑ **Aarhus Convention**
 - *Has provided guidance on access to information, public participation in decision-making and access to justice in environmental matters.*
- ❑ **World Trade Organization – Agreement on Sanitary and Phytosanitary Measures (SPS)**
 - *Has provided guidance on autonomous transboundary movements of Genetically Modified Mosquitoes in Articles 1, 2, 3 5 6 and 12.*
- ❑ **The International Plant Protection Convention (IPPC)**
 - *Has addressed risk analysis framework for quarantine pests including analysis of environmental risks and LMOs.*
- ❑ **The Food and agriculture Organization (FAO)**
 - *Has developed a code of conduct for the import and release of exotic biological control agents*
- ❑ **The National Plant Protection Organisation (NAPPO- RSPM)**
 - *Has developed guidelines for the importation and confined field release of transgenic arthropods for Canada, Mexico and USA.*

1d. Relevant African Regional Efforts

Leadership of the African Union through its NEPAD-AUDA Agency

- ❑ Created a High-Level Expert Panel to examine relevance gene drive technologies.
- ❑ Directed its agency NEPAD-AUDA to be at the forefront of efforts to guide and regulate gene drive research in Africa.
- ❑ Has conducted stocktaking of existing biosafety guidelines and frameworks in member states for suitability for gene drive research. Malaria control was identified as a priority area for research.
- ❑ Has urged African researchers to continue the development of gene drive technologies for malaria control and elimination and not to wait for technology transfer but rather anticipating its co-development.
- ❑ Is actively building regulatory capacity on biosafety and gene drive issues through the African Union Biosafety regulators forum
- ❑ Is forging strategic partnerships with national and international organizations and Programs in technology development and strengthening regulatory systems.
- ❑ Is promoting regional platforms to help manage the potential for transboundary movement.

2. Administrative System

Responsible institutions

- Uganda National Council for Science and Technology (UNCST)
 - ❖ National Biosafety Committee (NBC)
- MoSTI
- Ministry of Health
 - Uganda Virus Research Institute
 - Institutional Biosafety Committees (IBC)
- National Environment Management Authority (NEMA) – CBD Focal Point
- Ministry of Water and Environment
- Ministry of Trade
- Ministry of Justice and Constitutional Affairs
- National Biosafety Committee (NBC)
- Institutional Biosafety Committees (IBC)
- Institutional Ethics Review Committees

Role

- Screen GMO applications for completeness
- Undertake preliminary risk assessment
- Take decisions
- Consider existing situation of benefits vs risks
- Provide oversight for research

Key Guidance Documents

- WHO Guidance Framework for Testing Genetically Modified Mosquitoes
- Convention on Biological Diversity (CBD)
- Cartagena Protocol on Biosafety (CBP)

3. Risk Assessment and Risk Management System

Responsible institutions

- Uganda National Council for Science and Technology (UNCST)
 - NBC
- Uganda National Health Research Organisation (UNHRO)
 - Uganda Virus Research Institute
 - Institutional Biosafety Committees (IBC)
- National Environment Management Authority (NEMA) – CBD Focal Point
- Ministry of Water and Environment – Cartagena Protocol Focal Point

Role

- Provide oversight for research in RA and RM
- Identify potential adverse effects
- Estimate likelihood
- Evaluate identified risks
- Consider management strategies
- Assess overall impact
- Take decisions

Key Guidance Documents

- WHO Guidance Framework for Testing Genetically Modified Mosquitoes
- Convention on Biological Diversity (CBD)
- AHTEG recommendations on Risk assessment and Risk management
- Cartagena Protocol on Biosafety (CBP)
- Biosafety Risk Assessment Framework for Uganda

4. Inspections and Monitoring Systems

Responsible Institutions

- Uganda National Council for Science and Technology (UNCST)
 - NBC
- Ministry of Health (MOH)
 - Malaria Control Program
 - Uganda Virus Research Institute
 - Uganda National Health Research Organisation (UNHRO)
- National Environment Management Authority (NEMA)
 - Environmental Monitoring and Compliance Directorate – for EIAs
- Customs Departments.
- Ministry of Trade
- Institutional Biosafety Committees (IBC)

Role

- Ensure that activities are conducted safely
 - ◆ General surveillance
 - ◆ Case specific surveillance
- Facilitate notification process
- Check compliance with the law
- Undertake enforcement
- Set National standards
- Intelligence gathering

Guidance Documents

- WHO Guidance Framework for Testing Genetically Modified Mosquitoes
- Biosafety Containment Guidelines
- Guidelines on use of animals in research
- Guidelines for Institutional Biosafety Committees
- Guidelines for Research Ethics Committees
- Inspection Manual for GE crops

5. Public Information and Participation

Responsible Institutions

- Uganda National Council for Science and Technology (UNCST)
 - NBC
- National Environment Management Authority (NEMA)
 - Environmental Monitoring and Compliance Directorate – for EIAs
- Ministry of Health (MoH)
 - Malaria Control Program
- Institutional Biosafety Committees (IBC)
- Ministry of ICT and National Guidance
- Ministry of Justice and Constitutional Affairs
- Ministry of Trade
- Responsible Research Institutes

Role

- To disseminate information so as to create awareness
- To avail information upon request
- To nurture trust and confidence building and acceptance
- To facilitate consensus
- To facilitate decision making

Guidance Documents

- WHO Guidance Framework for Testing Genetically Modified Mosquitoes
- Convention on Biological Diversity
- Cartagena Protocol on Biosafety
- Aarhus Convention
- Institutional Information and Communication Strategies

Challenges to be addressed by social research

- Overlaps, inconsistencies, different values and orientations and diverse coordination mechanisms amongst organizations involved in drive governance.
- There is need for social science studies to clarify:
 - a) The different philosophies about risks of technologies and benefits of gene drive provisions in the CBD and WHO and its committees.
 - b) Indigenous knowledge available in gene drive
 - c) Benefits for individuals and communities in which the research takes place.
 - d) Appropriate societal mechanisms for whistle blowing and raising concerns on gene drive research.
 - e) Infrastructure necessary for a coordinated gene drive governance across national boundaries.
 - f) Appropriate models for consent and community engagement before field studies are conducted.
 - g) What constitutes an appropriate mechanism for Ugandan community engagement in gene drive

Recommendations

- ❑ Concerns about gene drive technologies can be resolved through appropriate regulation and oversight of by an empowered, critical and knowledgeable national stakeholders including ethics committees, GMO regulators, as well as a rigorous stakeholder engagement.
- ❑ There is need for increased awareness and collaboration between the two would help provide researchers with a clearer sense of the requirements and pathways they are expected to follow and how the two interact.
- ❑ There is need for capacity building and institutional building to inform regulatory infrastructure.
- ❑ There is need for an early engagement at regional level on issues of transboundary release of genetically modified mosquitoes.
- ❑ There is need to speed to generate evidence to accelerate the pace of the domestication of international guidelines at country levels.
- ❑ Need to involve the National Malaria Control Program in all gene drive activities.