Sub-theme:

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Title:

Phytosanitary and Risk Assessment Considerations during Introduction and Cross-border Movement of Transgenic Crops

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Introduction

- Recent advances in the world have enhanced development and trade in commodities and plant varieties developed using recombinant DNA techniques.
- According to the ISAAA in 2020, 29 countries planted biotech crops in 190.4 m-Ha.
- Out of this were 7 African countries - South Africa, Sudan, eSwatini, Malawi, Nigeria, Ethiopia and Kenya.
- Commercial Introduction of **transgenic varieties**, encompasses several considerations; **food and feed safety assessment, environmental impact assessment, biosafety assessment and variety performance**
- **ISPM No. 11 (*Pest risk analysis for quarantine pests*)** has also provided considerations for risk assessment during cross border movement especially when there is potential pest risk, or tendency to invasiveness or pest pressure or reduction of the same.

Introduction cont'

- Several African countries have considered the Global regulatory instruments such as risk assessment standard by the **IPPC,** Food safety assessment guidelines by **Codex Alimentarius,** Consensus documents by **OECD** and the Agreement in the Cartagena Protocol by the **CBD** and **domesticated or harmonized** them.
- The harmonization in some countries has provided a **one-stop shop** for risk assessment.
- In others domestication has been undertaken by adopting more than one avenues for risk assessment including:
  - Biosafety and food safety assessment by the Biosafety Authority
  - Environmental impact by the Environmental Agencies
  - Variety performance assessment by the variety release Agencies
  - Socio-economic consideration by other agencies including Policy makers
- This review outlines risk assessment considerations during introduction and cross-border movement of transgenic crops and proposes recommendations for considerations that can ease international trade.

Problem Statement

- Evolution of regulatory processes has not moved at the same pace as the expansion of global acreage in Africa.
- Global regulatory instruments have been implemented or domesticated in diverse ways in Africa leading to increased time and cost.
- Different National Regulators can provide synergy during risk assessment and opportunity exists to harmonize the same in a similar manner that phytosanitary standards have harmonized cross border movement
- There is therefore need for integrating phytosanitary and risk assessment considerations for transgenic crops to align with the framework employed on conventional crops for ease of movement and cross-border trade in commodities and crop products

Justification

- Conventional **regulated articles** are moved with **import permits** and **phytosanitary certificates**
- Commodities developed with r-DNA require extra approval from the Biosafety agencies, and the **nature of documentation or certification** required to accompany the phytosanitary certificate or embedded in the import permit **varies widely across trading partners**.
- Plant material classified as quarantine often are accompanied by a quarantine labels
- Due to perceived risks, r- DNA commodities, while using **same import permit** and **phytosanitary certificate** as provided **in ISPM No. 20** (*Guidelines for a phytosanitary import regulatory system*) and **7** (*Phytosanitary certification system*), are often **classified as quarantine** and no other label exist
- At the country level, r-DNA varieties as opposed to conventional ones require biosafety risk assessment, environment impact assessment, pest risk analysis, food safety assessment, when introduced from potentially high-risk sources.

Objectives

- Review of existing risk assessment approaches in Africa and recommend approaches to enhance cross border movement for r-DNA commodities
- Review of extent of application, harmonization and efficiency of international guidelines for risk assessment in Africa

Methodology

- The presentation provides a review based on experience during implementation of the Water Efficient Maize for Africa Project that operated in **six African countries** in collaboration with National Agricultural Research Agencies and other partners including CIMMYT and Bayer Crop Science
- The review also consider the experience of the TELA Maize Project operating in **seven African countries** with the same partners
- Experience gained by the African Agricultural Technology Foundation operating in fifteen African countries is also considered.
- Part of the review information in this presentation is therefore from actual participation in Applications, Development and Introduction of r-DNA and other commodities in Africa
- The information is supplemented by review of existing work of other authors

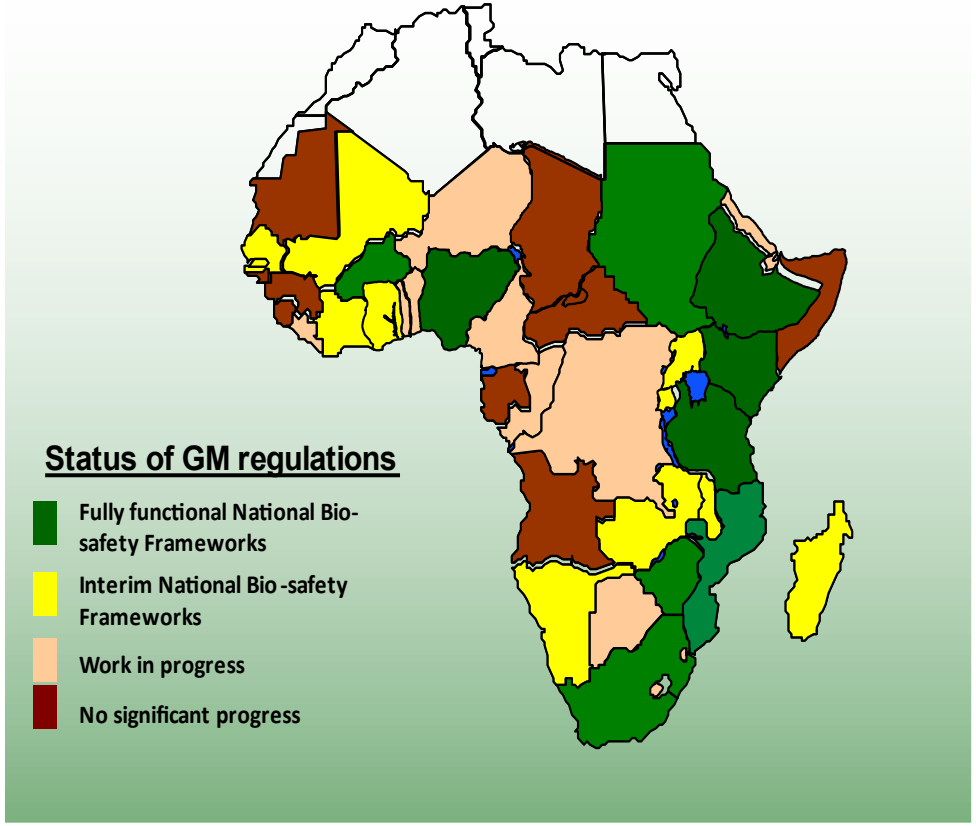
Methodology cont'

- The Authors have **reviewed** implementation approaches in Kenya, Uganda, Tanzania, Mozambique, Ethiopia, Nigeria, Ghana, Burkina Faso, Malawi and South Africa
- Information from the rest of Africa regarding status of regulatory frameworks has been considered from the work of Open Forum on Agricultural Biotechnology, A project of AATF, working with different partners in **9 African countries**
- Supplementary information has been obtained from free access sources by the AUDA NEPAD / ABNE, International Service for Acquisition of Agribiotech Applications – ISAAA and the Biosafety Clearing House – BCH of the Convention on Biological Diversity - CBD.
- Analysis of the risk assessment and cross border movement was undertaken through evaluation of existing international instruments developed through, IPPC, Codex Alimentarius Commission - CAC, CBD and OECD.

Results

Status of regulatory Frameworks in Africa

- Generally categorized into 4 as shown in the legend
- 7 African countries were cultivating r-DNA varieties in 2020
- Several others were trading in the r-DNA commodities directly or indirectly.
- *For instance* Countries neighboring South Africa, which leads in Africa in traded r-DNA commodities readily have consumer products with labels showing possible ingredients of r-DNA varieties.



Results cont'

- After the breeding, confined field trials (CFTs) are performed to determine efficacy of the traits
- It is possible to make an application for general release when CFTs have been carried out in another country, but this route is usually not followed even for a trait like **MON 810** that has been in cultivation in more than 15 countries since 1996.
- After CFTs, **review of general release application** usually lasts upto 270 days (9months) in countries that have adopted the timeline provided in the Cartagena Protocol of the CBD
- Several countries require **Environmental Impact assessment** which may precede the NPTs or which can be undertaken concurrently where feasible.
- These 2 steps easily lead to institutional divergence of mandates affecting the duration of approval
- The overall cost of introduction of r-DNA varieties without breeding costs, will generally cover, the running of CFT for a minimum of 2 seasons, Application fees, regulatory charges for monitoring and compliance, EIA assessment, VCU fees and public participation costs.
- The total for a single variety will be approximately USD60,000.

Results cont'

Steps of risk assessment in different countries

- Whereas a number of countries provide timeframes and cost for the risk assessment and review process, the duration will vary from 6 months, 2 years and 6 years in Kenya even where the law explicitly provides the timelines. An example of duration variation is shown in the table below:

Country	Risk assessments required	Duration of Application	Longest Duration (including Clock stoppage)	Total No. of approvals CFT, Lab , Import-Export, Transit Commercial
South Africa	Biosafety, VCU, DUS	30-120-270	>2yrs	>4,000
Kenya	EIA, DUS, VCU, Biosafety, SEC	90-150days	> 6yrs	>78
Mozambique	EIA, DUS, VCU, Biosafety, SEC, MLT	270 days	>2yrs	>2
Nigeria	Biosafety, VCU, DUS	270days	<2yrs	>28

Results cont'

- There is an inherent risk of **multiple layers of risk assessment** and **un-defined review duration, changing costs, coupled with socio-political considerations,** becoming new frontiers of non-tariff barriers to trade and impediments to technology adoption which,
- If they carry their day in r-DNA commodities, they may also find their way into emerging technologies such New Breeding Techniques.
- Targeted **mutagenesis techniques** such as oligonucleotide-directed mutagenesis (ODM), zinc finger nuclease (ZFN), meganuclease technique, transcriptional activator-like effector–nuclease (TALEN), and gene silencing techniques such as clustered regularly interspaced short palindromic repeats (CRISPR) have been treated in the same manner as r-DNA even where the legislation exempts mutagenesis.
- Traits, widely traded in commodities and cultivated in huge hectarage in many countries still undergo lengthy risk assessment even when data sharing could be sufficient while considering national sovereignty.

Conclusion

- The **data sets** for Pest risk analysis, Environmental impact assessment, Biosafety risk assessment and Food safety assessment do not differ significantly.
- There is merit in harmonizing the approaches into a one-stop review to ensure **predictable**, **cost effective process** and the **duration more definite** as is the case in **South Africa and Nigeria**.
- **Documentation** in international trade especially in Africa, to accompany phytosanitary certificates has largely been a **letter of declaration** of GMO-freedom or Attachment of the **Biosafety Approval** with varied formats and designs, an indication the Biosafety processes need to speak within the Phytosanitary standardization
- Standard advisory embedded in the PIP or existing in a regulation are the common "*additional declarations*".
- The overall **cost of introduction, trade and cross border movement** coupled with **inherent suspicion** have slowed rollout of benefits of commodities developed with r-DNA techniques.

Recommendations

- To encourage technology development, introduction and uptake, there is need to **harmonize the risk assessment**, ensure **predictable review** process and **duration** comparable to conventional varieties
- There is need to ensure that **cross border trade,** while using regular international standards for phytosanitary measures, does not discriminate commodities that have been assessed and found safe for use, on the basis of their method of development even if the method is r-DNA or NBT.

Acknowledgements

Theme: *"Enhancing Phytosanitary Systems for Healthy Plants, Safe & Sustainable Trade"*

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