

Developing Biosafety Regulations in Developing Countries

Experiences from Africa

Margaret Karembu, PhD
Director, ISAAA AfriCenter
mkarembu@isaaa.org

Historical Background

- Abstract – **regulations in absence of products**



- Precautionary Approach – emphasized **RISKS**
- African “Model Law” on Biosafety – **extreme interpretation of PP = stringent liability & redress**

Biosafety Frameworks

Common Features

POLICY

**REGULATORY
FRAMEWORK**

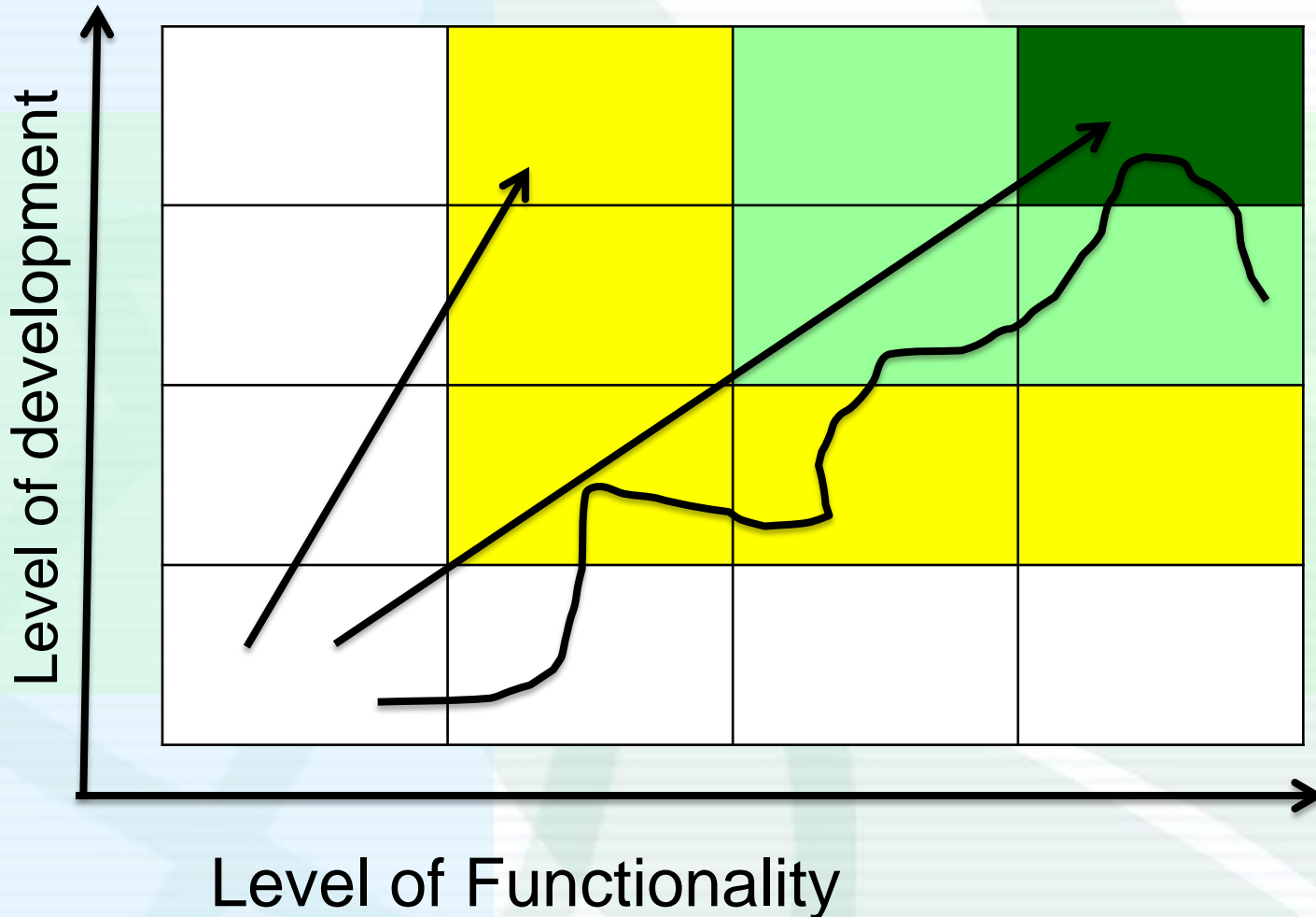
**INSTITUTIONAL
ARRANGEMENTS**

Common Policy Objectives

Apply Biotechnology to achieve:

- ✓ Economic Development
- ✓ Social Development
- ✓ Environmental Protection

Degree of Functionality: *Twists and Turns* (Ref F.Nangayo 2017)



Long
Tedious
Painful

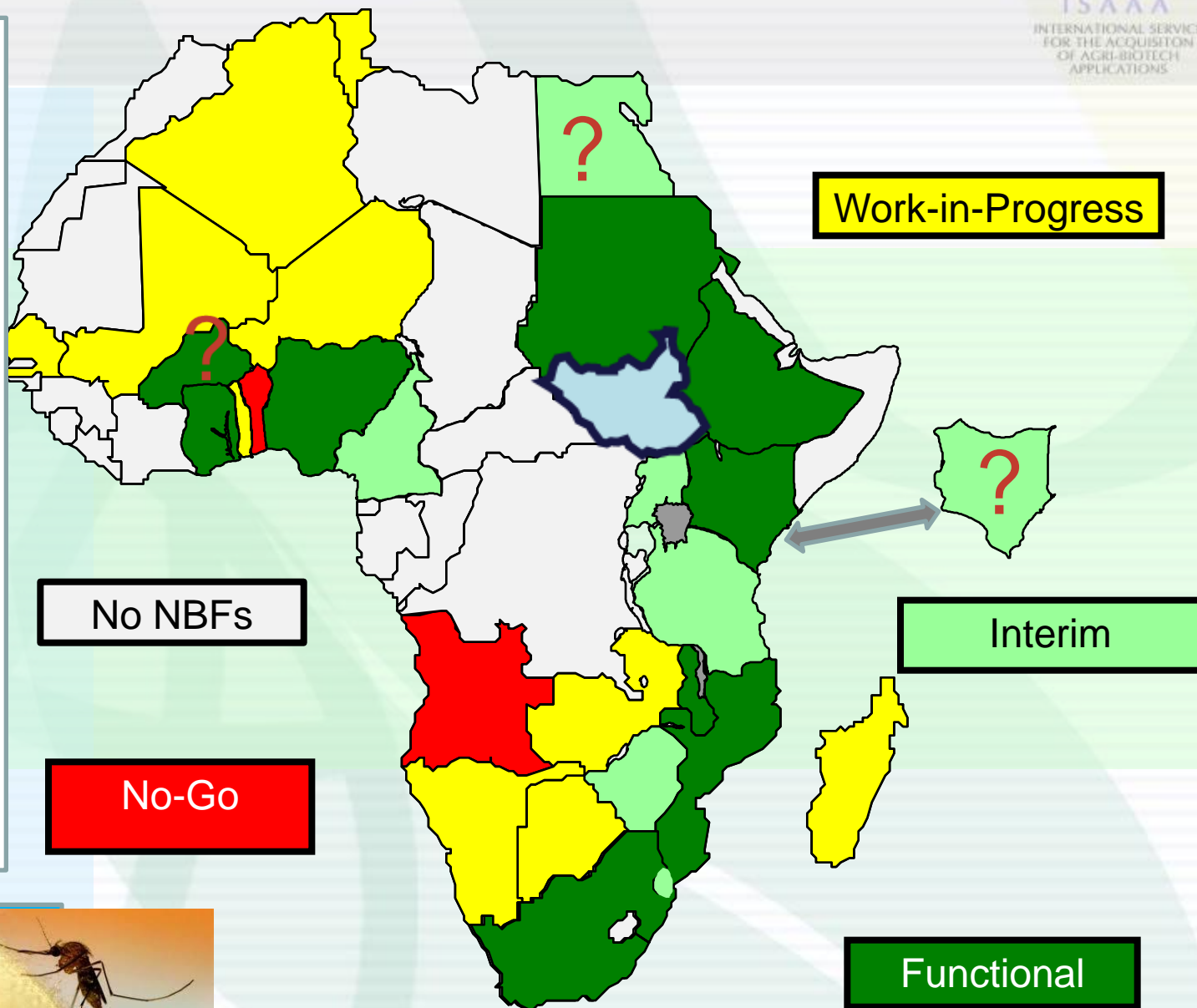
Many
extraneous
factors!
SEC
L&R
Co-existence

EU FACTOR

Regulatory Terrain for GM Crops in 2016

Countries with GM Crops' Activities

1. South Africa
2. Burkina Faso
3. Nigeria
4. Cameroon
5. Ghana
6. Ethiopia
7. Kenya
8. Tanzania
9. Mozambique
10. Malawi
11. Sudan
12. Egypt
13. Swaziland



GM ANIMALS?



Africa Biosafety Regulatory Processes:

General Observations



What has <u>not</u> worked	What has worked	Best practice
Abstract regulations in absence of products	Clear Government leadership (e.g. South Africa, Burkina Faso* Sudan, Ethiopia)	Mainstream biotech across all sectors; Case-by-case based on country priorities
Historical – highly precautionary despite 21 years of safe use = overregulation & high cost of compliance	Sharing Risk Assessment data and regulatory capacities emerging– Ghana/Nigeria (Bt cotton) Malawi/Kenya (NPTs)	Support implementation of harmonization efforts e.g. COMESA, SADC, ECOWAS..
Weak coordination among risk assessors in various agencies	Coordinated approach and experience accelerating regulatory approval process e.g. Malawi	Experiential learning through study tours; Capacity building partnerships

Reduction in time between Submission of CFT Application and Approval in Malawi



Africa Biosafety Regulatory Processes:

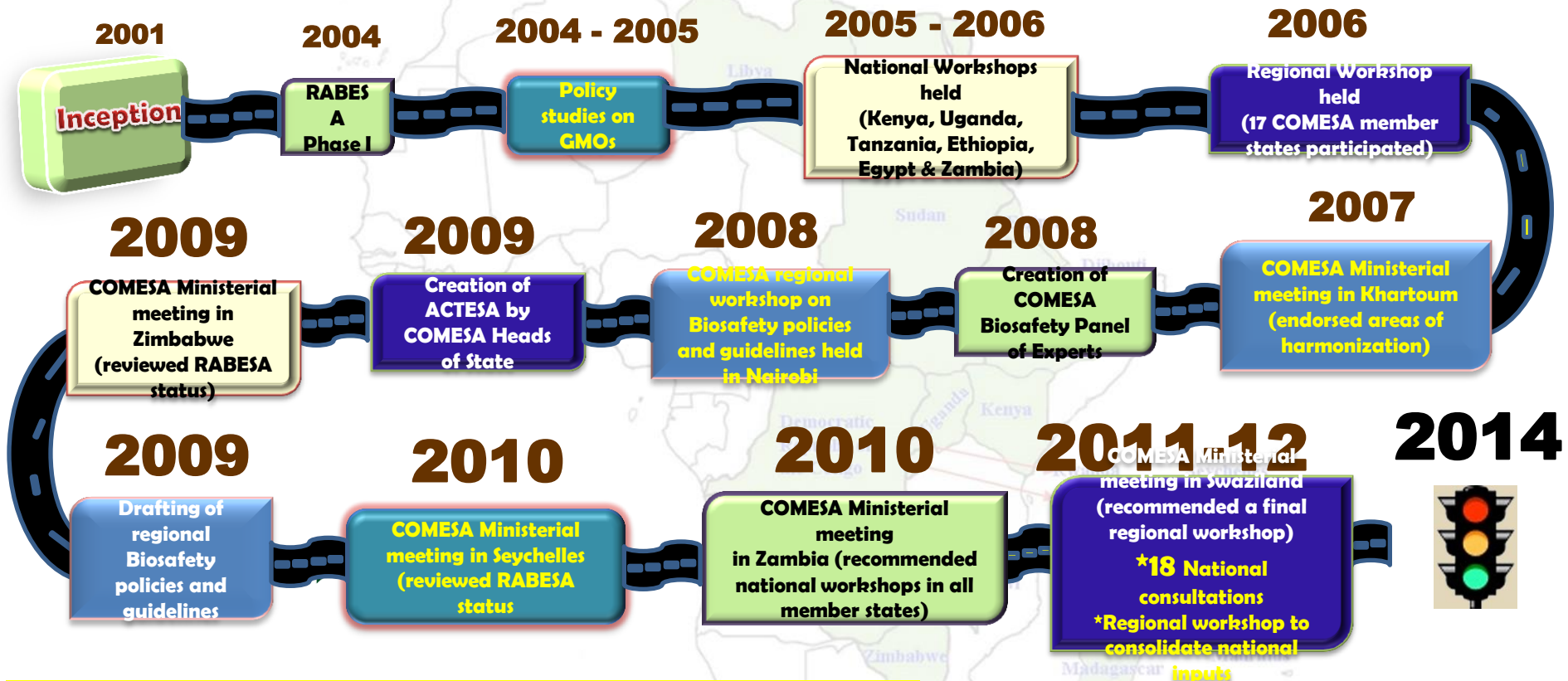
General Observations



What has <u>not</u> worked	What has worked	Best practice
Blanket regulatory process for GM crops and GM animals; recombinant vaccines	Selective; Animal and human vaccines subjected to same regulatory procedures?	Adapt regulatory regime for animal-related GM-programs; Case-by-case
Deeply held perceptions about private-sector, hence tight controls (<i>police-ing vs facilitative</i>)	Several Governments revising stringent, unworkable regulations	More public-sector support to develop products
Influence of activism delaying biosafety decision-making; Being reactive than proactive – <i>dancing to the tune...</i>	Secure Government commitments and political goodwill	<u>Intensify effective biosafety communication especially with new breeding tools</u>

COMESA PROGRAM

Regional Approach to Biotechnology and Biosafety Policy 2001 – 2014/COMBIP 2015...



OBJECTIVES

1. Regional Risk Assessment procedure
2. Trade with GM commodities – **no animals?**
3. Access to emergency food aid with GM content

MILESTONES

1. Regional biosafety policies and guidelines for commercial planting of GMOs, trade in GM products and access to emergency food aid with GM content drafted;
2. A communication strategy to create awareness about the COMESA harmonization agenda developed;
3. A biosafety roadmap to support countries establish and implement functional biosafety systems developed.



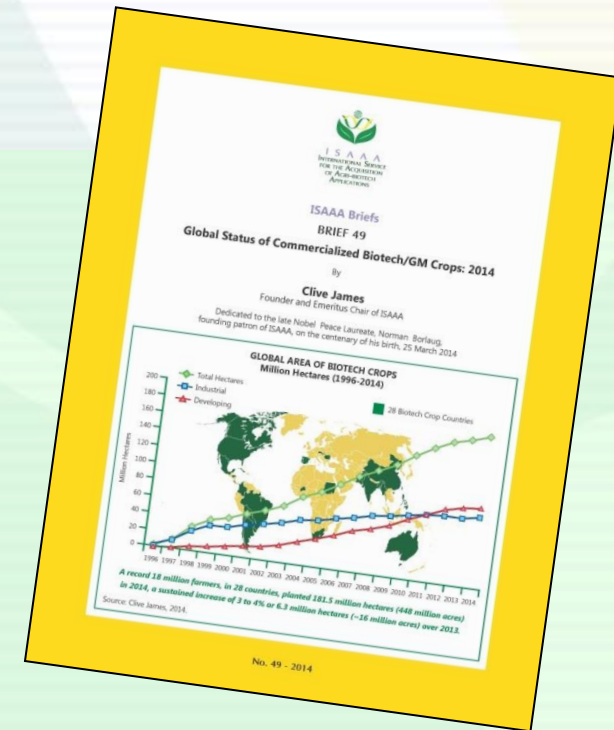
3 Key Challenges

1. Unpredictable political and policy environment to support vibrant biotech research on priority Africa challenges -mismatch of skills
2. Costly regulatory process beyond the reach of public- sector researchers (Public-private partnerships?)
3. Gross misinformation and media sensations creating fear and delayed policy processes

Conclusion

WII-FM (Shared values!)

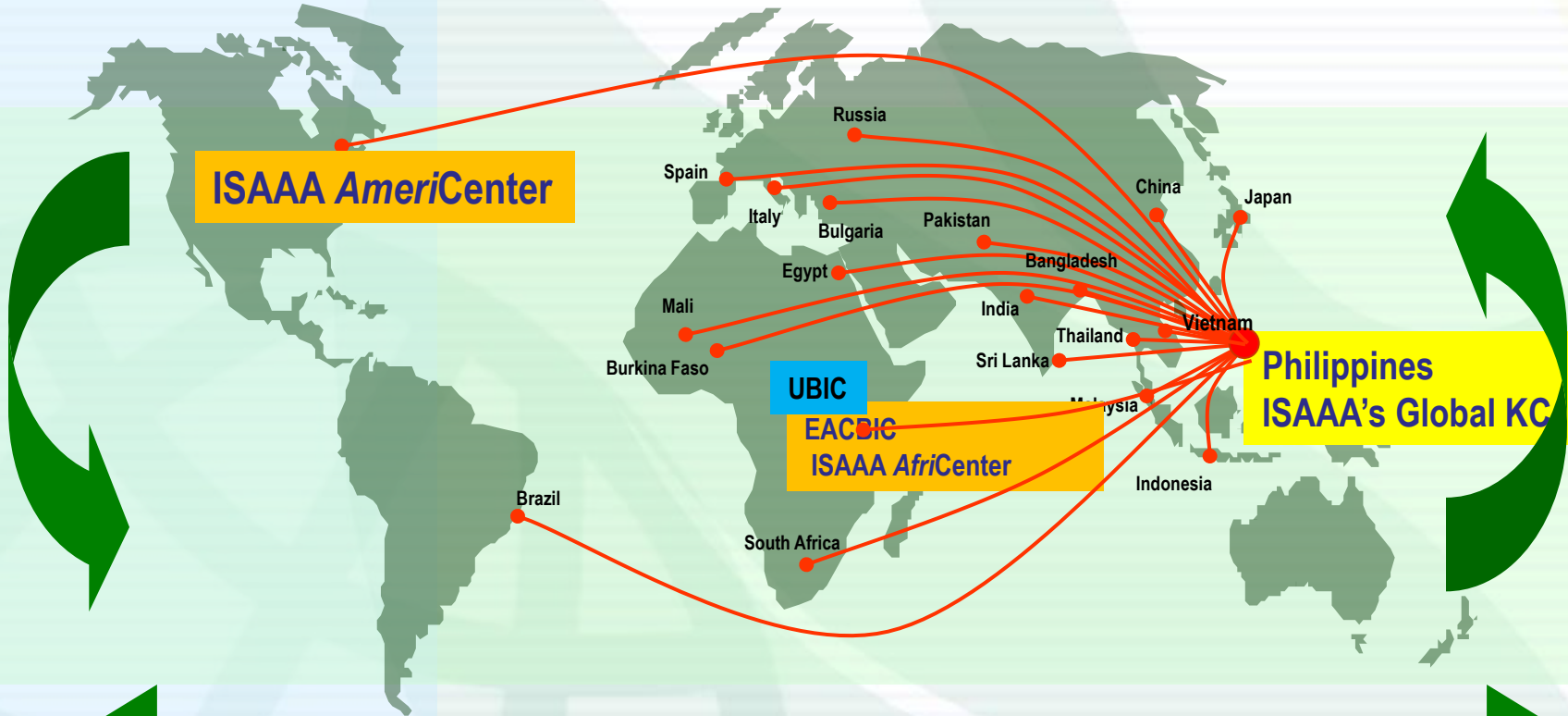
- ✓ ISAAA's global knowledge sharing initiative on agri-biotech applications
- ✓ Has constructed a GMO Approval Database to document global regulatory approvals of **biotech crops** in real time



Partnership in expanding global database with
Animal Biotechnology regulatory approvals?

ISAAA's Communications' and Global Knowledge Sharing Initiative

Network of 26 Biotech Information Centers - BICs



Dual Knowledge and Experience Sharing

Weekly Crop Biotech Updates

**"Glass is half-full NOT half empty
Think Opportunities!"**



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