STRENGTHENING REGULATORY CAPACITY OF AFRICAN UNION MEMBER STATES FOR GENETICALLY ENGINEERED INSECTS

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Outline of the presentation

- African Union and the New Partnership for Africa's Development (NEPAD) Agency
- Status of GM crops and Biosafety laws in Africa
- Political authorization of harnessing technology for development
- Exiting programmes on regulatory strengthening in the African Union
- Experience with Genetically Engineered Insects
- Scope of regulatory requirements for Africa
- Support for release of genetically engineered insects in Africa

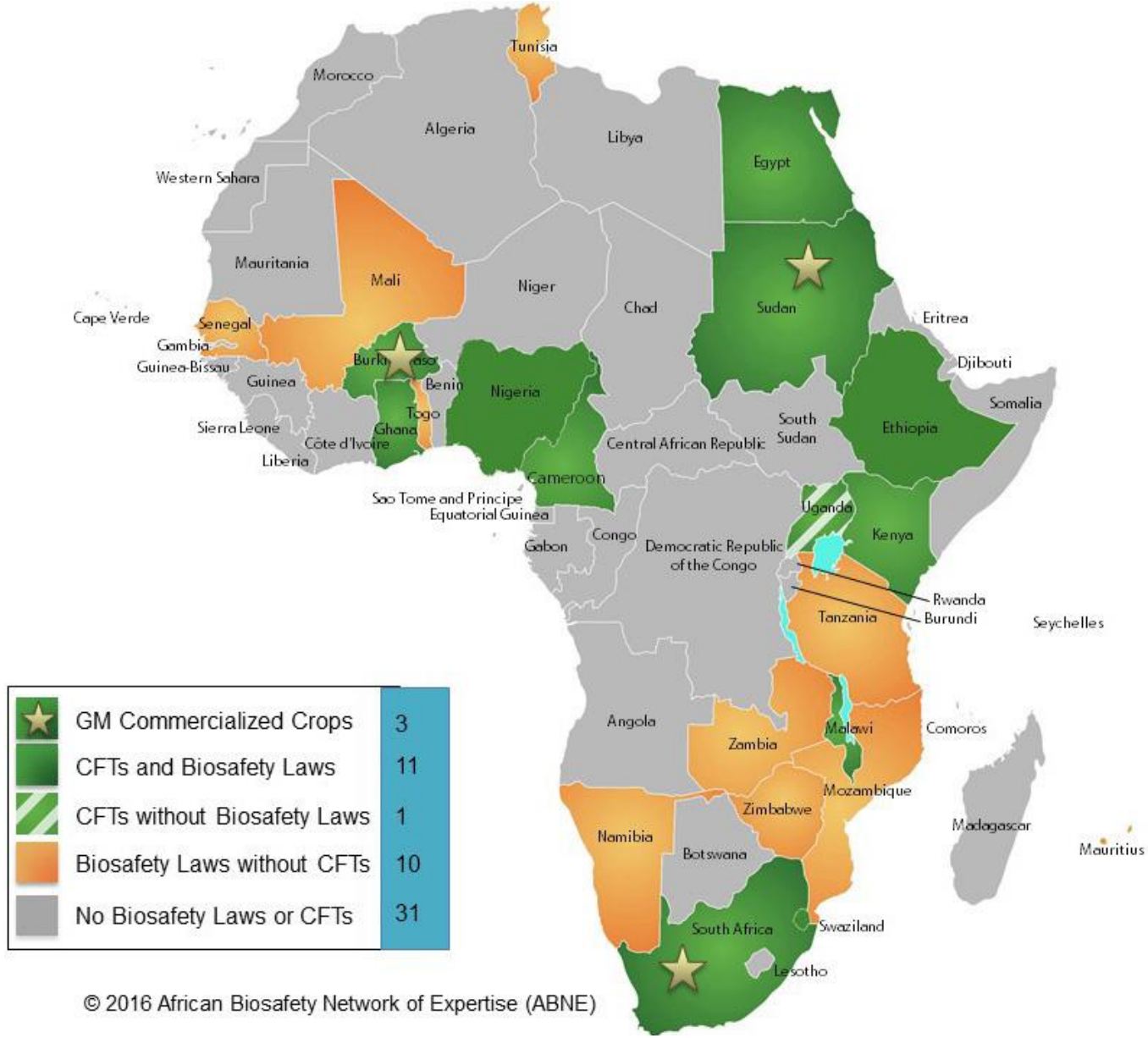
Africa Union

54 out of 55 countries are members of the African Union

NEPAD Agency

NEPAD is the Technical arm of the African Union spearheading the socioeconomic development programmes of the African Union

- **Coordinating** and **facilitating** implementation of continental programmes
- **Monitoring** and **evaluating** the implementation of programmes in the AU
- **Advocating** on the AU and NEPAD vision, mission and core values
- **Mobilising** resources and partners in support of programmes



Africa harnessing innovations

- Africa is in a period of transition which demands harnessing safe advances made in science-based innovations

- African Union adopted a High-Level Panel report on modern biotechnology entitled, *Freedom to Innovate*, which advocated for a co-evolutionary approach where technology development goes hand in hand with regulation

- Most AU member states are Parties to the Cartagena Protocol on Biosafety (CPB)

African Union Decisions of July 2016

- Endorsed that the NEPAD Agency should advise member states on matters of technology prospecting including regulatory and ethical requirements that need to be put in place in order for the continent to benefit from emerging technologies for economic development and environmental sustainability

- Further directed the NEPAD Agency to establish a system for obtaining expert contribution on matters of technology development, acquisition and deployment for economic development

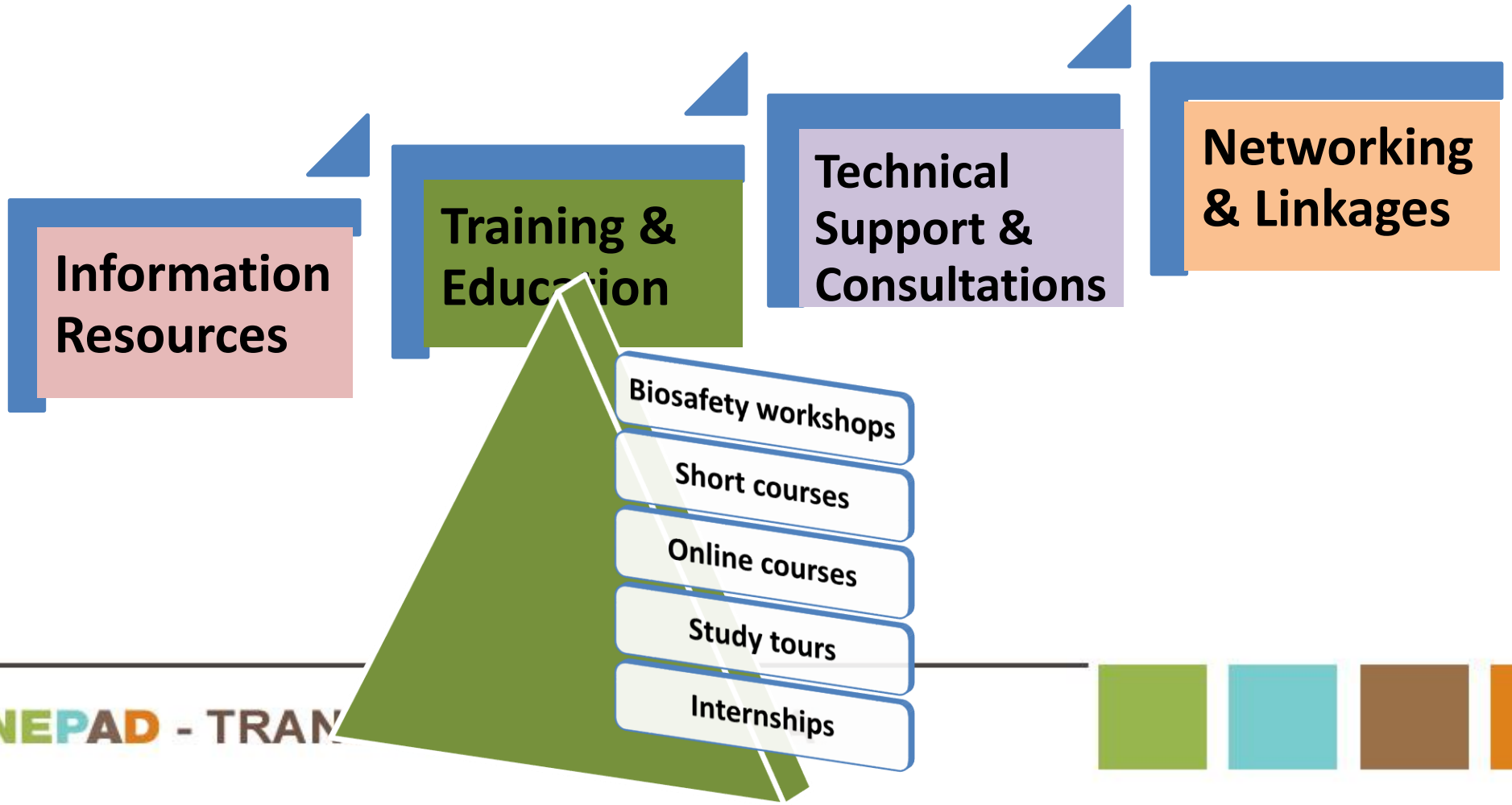
Exiting programmes on regulatory strengthening in the African Union

- African Biosafety Network of Expertise (ABNE) – Agriculture
- African Medicines Regulatory Harmonization (AMRH) - Health

African Biosafety Network of Expertise (ABNE)

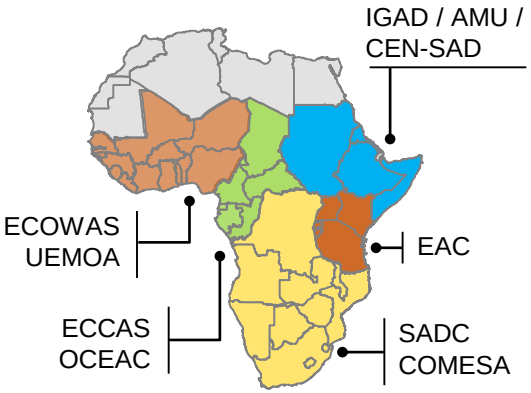
- ABNE was conceptualized by NEPAD Agency, MSU &BMGF
- **Mandate**: to build functional biosafety systems in Africa.
- Maintain credibility by fact-based neutrality
- Focus mainly on regulators

ABNE's service delivery platform



AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)

- Is a partnership initiative formalized in 2009 and launched in the East African Community countries in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda)
- Partnership includes African countries (regulatory authorities) and regional blocs, WHO, NEPAD, Gates Foundation, DFID, PEPFAR/USG, GAVI, Swissmedic, SDC, World Bank
- Aims to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one
- Proposes to start by harmonizing and streamlining technical requirements for product registration, leading to increased and timely product access
- Creates a platform to build African regulatory capacity by region



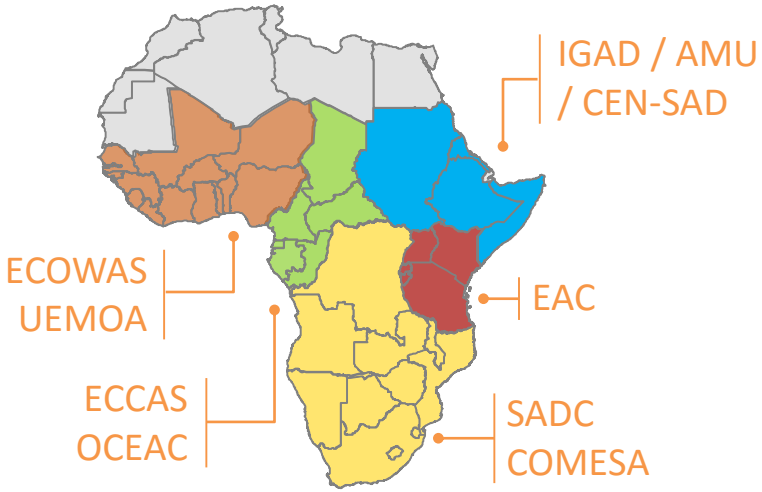
Initial focus

Regional regulatory platforms

- Harmonized standards (technical requirements / guidelines)
- Joint and regional dossier assessments / GMP inspections
- Work sharing / pooling of resources
- Streamlined decision-making processes

- ***Reduced registration cycle time...***
  ...starting with generics
  ...extending to other product categories
  (NCEs, vaccines, diagnostics)
- ***Extending to other regulatory functions over time*** *(clinical trials, safety surveillance, etc.)*
- ***Extending to other African regional blocs***

African Medicines Regulatory Harmonization (AMRH)

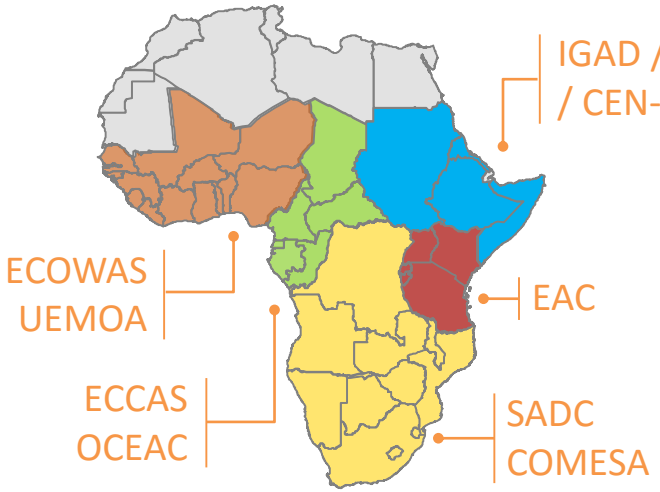


54 countries → 5 regions → 1 continent

Experience with Genetically Engineered Insects

- First candidate in the pipeline is Target mosquito but not yet introduced
- Regulatory applications with sterile males—Build regulatory experience and establish regulatory processes
- Application for contained use submitted and approved in Burkina Faso
- Other countries targeted for contained use are Mali and Uganda

Scope of regulatory requirements for Africa



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Support for release of genetically engineered insects in Africa

- Building regulatory capacity at national and Regional Economic Communities (RECs) levels
- Supporting the establishment and functioning of relevant regulatory bodies i.e. Institutional Biosafety Committees (IBCs), National Biosafety Agencies (NBAs), National Biosafety Committees (NBCs) and regional regulatory agencies
- Conducting study tours for key players at political, regulatory, scientific and community levels
- Supporting preparation and review of policies and guidelines especially at regional level
- Enhancing and advocating for community engagement and communication

Thank You!