



“How enabling policy can facilitate uptake of biologicals: The EAC harmonization process”

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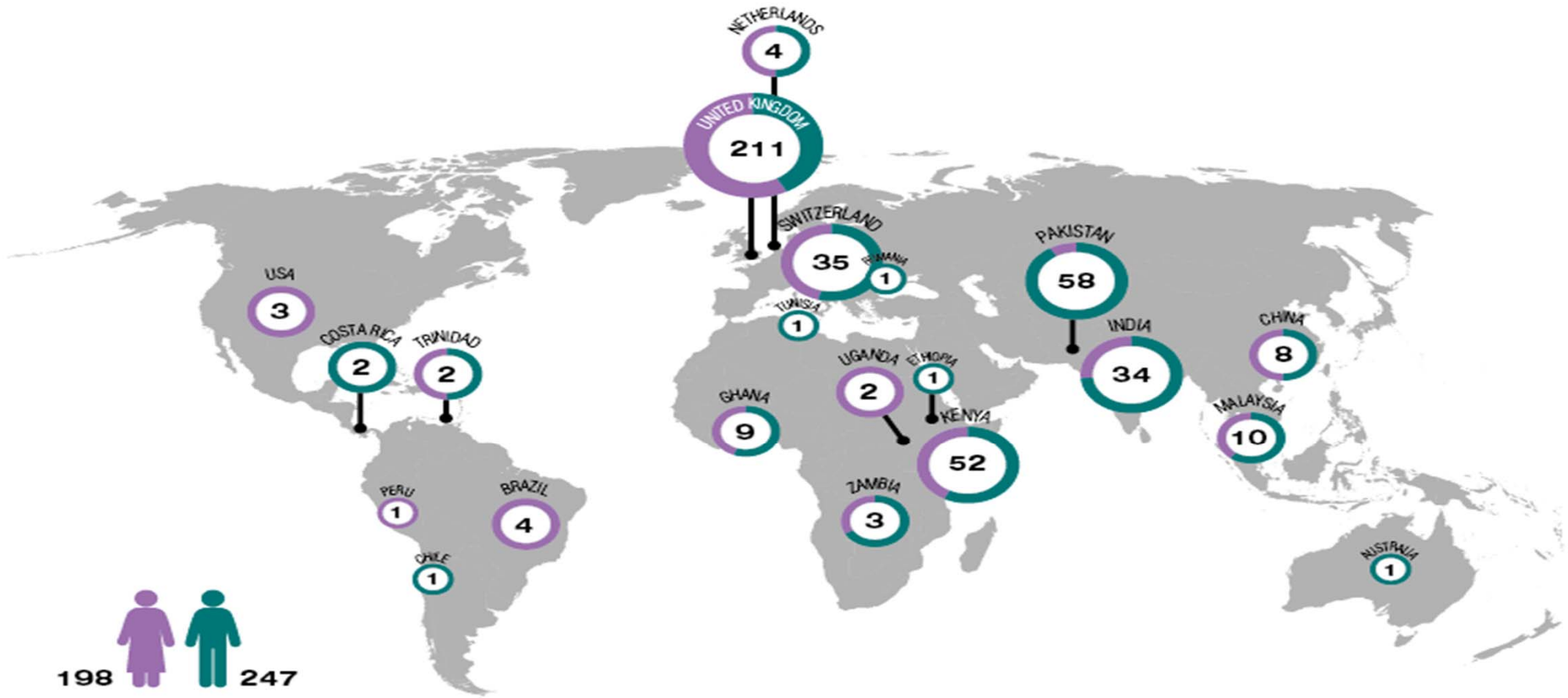




CABI in Brief

- **Not-for-profit** intergovernmental organisation established in **1910** by a UN treaty
- Provides scientific expertise and information about **agriculture** and the **environment**
- Expertise in: scientific publishing and international development
- Owned by **49 member countries**

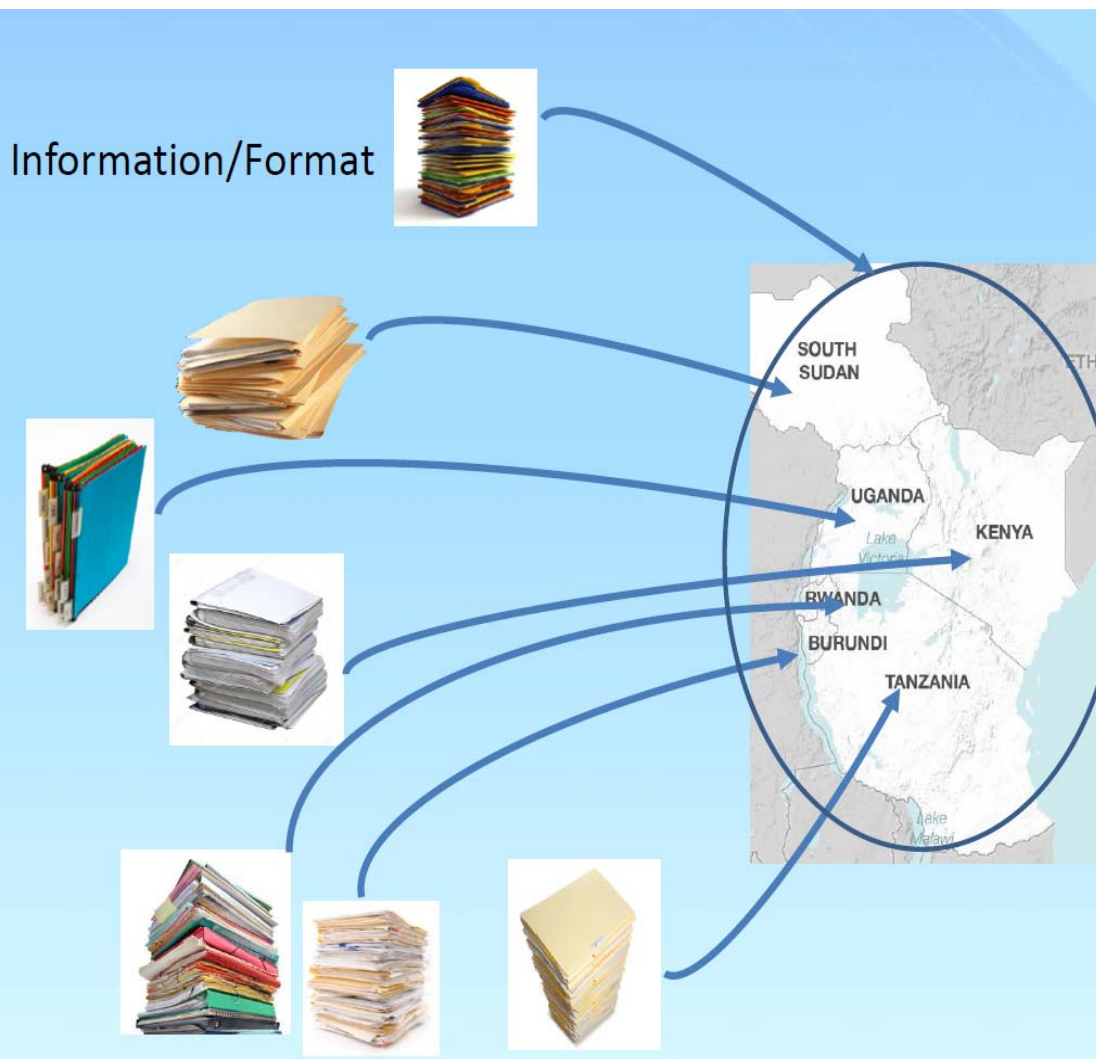
Global reach We have 480+ staff across 21 locations worldwide



Background to biopesticide harmonization in EAC



- EAC partner states recognize a need for increased use of safer and lower risk crop protection products
- Imports of agrochemicals more than doubled within four years from **6,400 tonnes in 2015 to 15,600 tonnes in 2018** (PCPB, Kenya)
- Varied and **inadequate regulatory regimes** an impediment to effective uptake
- Renewed attention on the use of **safer pest control alternatives** especially biopesticides and other biocontrol agents



Why the need for harmonized guidelines?

- Under the current regulatory regimes, the registration system for biologicals a challenge to regulators
- No specific **legislation** in the EAC governing the registration of biologicals
- Biologicals usually subjected to the same requirements as the conventional pesticides



Objectives of the harmonized guidelines

- Provide EAC partner states with a **harmonized framework** for registering biopesticides and biocontrol agents
- Facilitate **mutual recognition** & sharing of data for registration of biopesticides & biocontrol agents amongst the EAC partner states
- Facilitate **best practice** in the registration of biopesticides & biocontrol agents for plant protection

Scope of the guidelines

- **Micro-organisms** (bacteria, fungi, viruses, protozoa)
- **Macro-organisms** (predators and parasitoids, insects and mites)
- **Biochemical pesticides** (botanicals and semiochemicals).
- Exclusions: Microbial, macrobial, botanical and semiochemical biopesticides derived from or based on genetically modified organisms (GMOs) are NOT covered
- Biochemical pesticides that may pose adverse effects on human, non-target organisms and environment shall be evaluated as conventional pesticides. BUT in some cases waivers will be granted where there is sufficient evidence that there are no safety concerns

Registration use categories

- **Experimental use permit:** status granted for experimental use prior to submitting application for full registration
- **Full registration:** When all registration requirements have been met
- **Temporary/Emergency registration:** allowing the biopesticides and biocontrol agents to be used, while still in process of fulfilling registration requirements.
- **Provisional registration:** registration status granted pending supply of further data required by the registration authority

Some of the requirements for microbials & botanicals

- Scientific name and common name when applicable
- Strain or isolate of microbials
- Source or origin (country, where its isolated from, ecological habitat)
- Physical chemical properties of the product
- Biological properties
- Composition of the product
- Production process and quality control
- Test procedure and criteria for identification
- Impurities and contaminants if applicable
- Shelf life
- Quality Verification report
- Field efficacy studies on proposed use
- Laboratory studies for bioassays
- Packaging material
- Labels and leaflets
- Infectivity and pathogenicity (Tier 1, Tier 2 and Tier 3)
- Acute toxicity studies
- Ecotoxicology fate (Tier 1 and Tier 2)
- Environmental fate; in soil, surface & ground water
- Residue data
- Procedure for destruction and decontamination

- The 13th Sectoral Council on Agriculture and Food Security in September 2019 adopted the guidelines and has urged EAC partners states to use them


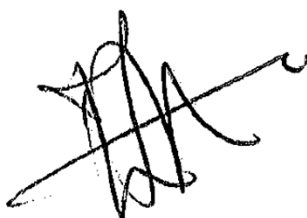
The Sectoral Council;

a) **adopted**

- i) **the EAC guidelines on data requirements for the registration of Biopesticides and Biocontrol agents for Plant Protection and urged Partner States to implement them;**
- ii) guidelines for designating testing centres for pest control products and urged Partner States to implement them;
- iii) guidelines for Confidential Business Information (CBI) protection and urged Partner States to implement them; and

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Next steps in implementation?

- Domestication of the guidelines (Ref: EAC/SR/18/2019 into national laws of the six (6) EAC partner states
- Pilot the guidelines with selected biological control products across two or more countries
- Create awareness of the guidelines among sector players
- Track the status of implementation of the guidelines and address any problems that arise in interpretation by partner states
- Have these guidelines made the registration process easier or created new complications?

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 terima kasih

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