Harmonization efforts on pesticide regulation under the East African Community

By Paul. N. Ngaruiya (Dr), Pest Control Products Board (PCPB)

Harmonization workshop, Alexandaria, Egypt, 30th March – 2nd April 2009
Scope

- Introduction
- What has been done
- Challenges
- Recommendations on way forward
Introduction

Until 1977, the regulations on pesticides were governed by the provisions of the Pesticides Control Act of the East African Community.

Thereafter each state enacted Acts of parliaments to regulate pesticides eg under the Pharmacy and Poisons Act, Cap 244, then the Pest Control products Act Cap 346, of 1982.
Introduction

Political and legal support: In Nov. 1999, the Treaty for the establishment of the East African Community was signed by the 3 heads of state-Kenya, Uganda and Tanzania

Article 108 on Plant and animal Disease Control states: Partners states shall:

- a) Harmonize policies, legislation and regulation for enforcement of pest and disease control
- b) Harmonize and strengthen regulatory institutions
- e) Adopt common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines etc

Structure established
Application forms for registration of conventional pest control products

Presented in National workshops and comments harmonized at EAC
Registration of conventional PCPs

The registration requirements were developed pursuant to Article 108(a) and (e) of the Treaty for the Establishment of East African Community.

The requirements were aimed at assisting the relevant regulatory authorities in the Partner States to carry out a thorough evaluation on safety, quality and efficacy of Pest Control Products before authority to trade in the products is granted.
Registration of conventional PCPs

Partner states recognized:

- Existence of various types of pest control products with differing toxicological profiles, physicals and chemical properties, biological properties, origin, persistence etc.

- There are products for crop protection, animal health and public health.
Definition

Conventional Pest Control Product” means a product that has been synthetically produced for directly or indirectly controlling any pest—excludes biopesticides.
General Provisions

- All partner states should ensure that all new pest control products are subjected to a thorough evaluation process before they are authorized for any use.
- The application forms should be used by all applicants intending to register conventional pest control products in the partner states.
No person shall import, export, manufacture, formulate, package, distribute, sell or store or be in possession of a pest control product unless it has been registered for use in the partner state.

Samples of the pest control product must be provided to the regulatory authority during the registration process.

All partner states will inform other regulatory authorities of new products that have been registered.
General Provisions cont’d

- Information on newly discovered hazards, safety concerns, or ineffectiveness attributed to new or already registered products will be relayed to the partner states without delay.

- Information on presence of smuggled, counterfeit, adulterated, unregistered pest control products will be distributed to the relevant authorities.

- Information on banned, severely restricted, deregistered and suspended or withdrawn for any reason will be relayed to the partner states without delay.
General Provisions cont’d

Every application must be accompanied by:-

- (a) the application fees prescribed by the relevant regulatory authority.

- (b) 3 copies of the draft label as per the label requirements

- (c) a technical dossier as per Lists I and II.

An applicant who is not ordinarily resident in the Partner State must appoint an agent who is permanently resident in the Partner State and duly recognized.
Layout

- Divided into 4 sections
  - Harmonized Application form A1
  - Registration requirements for active ingredient, List I
  - Registration requirements for the formulated product, List II
  - Guidelines for active ingredient and formulated product
Requirements for ai

- Dossier index for active ingredient (List I)
  - Identity of active agent
  - Physical chemical properties
  - Toxicology
  - Ecotoxicology
  - Behaviour in the environment
Requirements for Formulated product; List II (Dossier index)

- Identity
- Physical chemical properties
- Toxicology
- Emergency in case of accidental exposure
- Emergence in case of fire/spillage
- Intended uses
- Residue data from supervised trials
- Commercial label,
- Proposed packaging
- Procedures of destruction and decontamination
PROCEDURES FOR EVALUATING THE EFFICACY OF PEST CONTROL PRODUCTS FOR PLANTS

Presented in National workshops and comments harmonized at EAC
Efficacy of pest control products for plants

- The procedures set out guidelines for carrying out the efficacy trials and for the presentation of research findings.
- Efficacy evaluation enables the registration authorities to evaluate the benefits to be gained from new products and to weigh those benefits against potential hazards due to their introduction.
- In the past, reports of efficacy trials have not been uniform.
- All trials must be authorized by the relevant national registration authority.
- The scientist is obliged to liaise closely with the relevant national registration authority throughout the trial period.
General Provisions

- All Partner States should ensure that all new pest control products are subjected to a thorough efficacy evaluation before they are authorized for any use.
- Samples of the pest control product must be provided to the testing institution on approval by the regulatory authority.
- New information on ineffectiveness of already registered products will be relayed to the Partner States without delay.
- The report should be submitted in hard and soft copies to the respective regulatory authority in the Partner States.
Guideline on Conduct of trial and reporting

- Divided into 4 sections
  - Introduction
  - Objectives
  - Materials and methods (How to conduct the registration trials)
  - Presentation of research findings
Conduct of trial and reporting

Materials and methods
- It should give a description of methods used and citations of relevant reference methods.
- should include the common and trade names of the candidate product,
- source of product,
- Formulation & concentration of the active ingredient,
- test crop/commodity, target pests,
- experimental design
- methods of statistical analysis.
Conduct of trial and reporting

Recommendations

- State clearly whether the product is suitable for registration for the stated use.
- The scientist should clearly recommend:
  - Application rates
  - Time of application
  - Frequency of application
  - Spray volume
  - Pre-Harvest Interval
  - Any other observations
- State clearly whether the data met the 3 consecutive season criteria.
LABELLING

- Presented in National workshops and comments harmonized at EAC
- Every pest control product, distributed, sold, exposed, offered for sale or for research purposes shall bear on the container thereof, a label in understandable English and Kiswahili or any other authorized language.
- All labels shall be approved by the relevant authority prior to use.
General Provisions

- Two types of labels shall be recognized by the Partner States
  - Commercial labels
  - Provisional labels
Commercial labels

- Pest control products destined for commercial purposes shall have a label with a principal display panel and a secondary display panel.

- Display panel means part of a label applied on or affixed to the package but does not include leaflet or brochure unless it is part of the label.
Principal Display Panel cont’d

Example

REGISTRATION NO:
Country Code (Ug/Ke/Tz); Pesticide category e.g. C for chemical, B for Biopesticide; Year of registration in four digits; Registration number in four digits; Type of pesticide e.g. RO – Rodenticide, AV - Avicides, AC - Acaricides, HE - Herbicides, IN - Insecticides, FU - Fungicides; Registration Status e.g. E for experimental registration, P for provisional registration, T for temporary and R for fully registered. For example a registration number for a Fungicide Fully registered in Kenya in 2005 will read as follows;

REGISTRATION No_ Ke/C/2005/0001/FU/R.

Others: , Trade name, Guarantee, Pictograms, net weight etc
Secondary Display Panel

- Brief description of product i.e. *classification, mode of action*,
- Directions for use that must include rates/area, compatibility,
- Information on timing of application,
- Use limitation,
- Crops/types of animals or species/area of use, (To include crops/animal pests and diseases for which the product is registered).
- Number of applications, spray volume,
- Preharvest intervals, compatibility, re-entry period should be provided.
- Others- Toxicological information, First aid, etc.
Challenges

- Different registration procedures – takes long come to a compromise
- Limited facilitation - eg 1 meeting in a year leads to loss of momentum
- Legal barriers eg for a document to be agreed upon and be deemed legal all partner states have to be present
- Language barriers
- Limited experience in certain areas eg MRL setting and residue trials
- Policy changes midstream
- Which committee to handle cross cutting issues eg Food safety
Recommendations on Global MRL harmonization

- Political support is paramount
- Institutional framework to provide for reporting and feedback mechanism
- Identify representative geographical areas for residue trials,
- Evaluation and Accreditation of trial institution
- More funding
- Legal support - e.g. treaty
Thank you