

CURRENT PESTICIDE REGISTRATION SYSTEM AND CHALLENGES IN ETHIOPIA

***BY TSEHAY AZAGE
PLANT PATHOLOGIST***

PRESENTED ON

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APHRD,MOA October 26, 20 11

A. Background

Definition of pesticide registration

- **Means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment.**

Objectives of Registration of Pesticides

To minimize the adverse effects of pesticides to humans ,animals, plants and the environment in general

By registering

- Relatively safe
- Locally effective
- Good quality pesticide

Legislation

Mandate:

- The MoA is mandated to Register and Control Pesticides
 - First by a single article included in the Plant Protection Decree No 56 of 1971 (article 5)
 - Later “Pesticide Registration and Control Special Decree No 20/1990 was issued in September 1990 and has been implemented between 1996 and 24th August 2010

Conti■ ■

- A new << **Pesticide Registration and Control Proclamation**>>
- **P. No. 674/2010** enacted August 2010.

Regulations and Directives

- A draft Regulation prepared
- No directives
- Guidelines- Compiled

B. Present organization on the Registration of Pesticide

Who is Involved?

- APHRD of the MOA
- Advisory Board (policy, rules etc) which includes
- ✓ Officer designated by the Minister (**Chairperson**)
- ✓ Officer in charge of pesticide Registration (**Member and Secretary**)

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- ✓ Representatives from
MOH, EPA, ECAE, EIAR,MLSA,ARC,
- The board (Can set up a technique committee)
- Inspector (with duties and responsibilities)
- And have
- Data base and Archive
- Pesticide Register (List of registered Pesti)



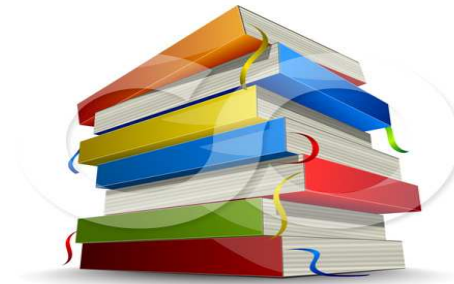
C. Procedure for Pesticide Registration

1. Data Requirement

- Based on SEARCH format and country specific requirements
- Has four parts
 - Application
 - Active Ingredient Dossier Index (List I)
 - Formulated Product Dossier index (List II)
 - Country specific requirements

SEARCH (Southern and Eastern African countries Regulatory
Committee on Harmonisation of Pesticide Registration)

Application



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- Applicant identification - Name of Registrant and local agent
- Status - formulator/importer
- Address
- Product trade name, function, intended use target pest, formulation, registration in SEARCH countries, active ingredients, composition, summary of toxicology on formulated products, packaging, Declaration

ACTIVE INGREDIENT DOSSIER INDEX (LIST I)

CONSISTS SEVEN PARTS

1.DESIGNATION

Common name, manufacturer or development code, chemical name, structural formula, empirical formula

2.Chemical and physical properties

Physical state, color, odour, density, solubility in water ,solubility in organic solvents vapour pressure, n-octanal/water partition coefficient, method of analysis, photolysis

Cont...

3. Toxicology

ADI, acute oral, dermal LD_{50} , Inhalation LC_{50}
Skin irritation, Eye Irritation, sensitization,
neurotoxicity, teratogenicity, mutagenicity

4. Ecotoxicology

LD_{50} , NOEL, Reproduction 2 species of birds, 2
species of fish, daphnia, algae, bees, earth worms

Conti..

5. Behavior in environment

Behavior, ways of degradation, degradation products
in soil, water, DT_{50}

6. Mode of action

7. Residue in the plant

Major metabolites

MRL codex on the crop to be registered

MRL country on the crop to be registered

Method of residue analysis

FORMULATED PRODUCT DOSSIER INDEX (LIST II)

Consists five parts

1. Physical and chemical properties

Physical state/formulation type, color, odor Storage stability, shelf life, density, flammability Flash point, compatibility with other products, PH, oxidizing properties, corrosiveness, water content, watability, solubility in water, foaming, particle size, Suspensibility, emulsion stability, volatility, Method of formulation analysis

Conti..

2. Toxicology

- Acute oral LD₅₀, Acute dermal LD₅₀ on rats
- Skin irritation and eye irritation on rabbits
- Sensitization in guinea pig
- WHO classification

3. Emergency procedures in case of accidental procedures or poisoning

4. Emergency procedure in case of fire /spillage

5. Uses

Country specific requirements

- Local efficacy data generated from research institutions or universities
- Sample of the technical grade and the formulated product- 2 lots of 500 gm or ml of the formulated product and one lot 1 gm of the technical grade
- Agency agreement (between local agent and the registration holder)

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- Third party batch certificate of analysis from accredited laboratory (if the analysis is done by the registrant itself ,the registrant should be GLP certified)
- Manufacturing license from the country of origin
- Label in English and Amharic according to Ethiopian pesticide registration guideline
 - One panel label - for 5 Kg Liters packages or less and leaflets for the same
 - Three panel label - for greater than 5 liter (Kg)

D. Authorization of Registration

- Submission of Application + Dossier Two copies of the dossier (List I and List II)
- Local efficacy report (EIAR or other Institutions with research mandate
 - a. Administrative check
 - b. Technical evaluation (APHRD)
(Experts from different discipline within the department will give recommendations)
Incomplete back to Applicant



C. The Director /Process owner

The final decision made by the Director.

d. Notification of decision to the applicant (Registration/ Rejection)



e. Letter of notification if rejected

f. Certificate of registration (payment 1000 birr)

E. Registered Pesticides

Registered pesticides by use category (until Jan 2011)

- Insecticides	=	114	(42.8%)
- Herbicide	=	61	(23.00%)
- Fungicides	=	63	(23.70%)
- Others	=	28	(10.50%)
Total	=	266	

F. Validity of Registration

The registration of a pesticide shall be valid for five years from the date of issuance of certificate of registration.

G. Renewal of Registration

- Procedure
 - Application made by applicant with the report of import for the last 5 years before 90 days of expiration (**import volume, area of distribution, information on the effectiveness of the pesticide etc**)
 - Assessment made by inspectors if any problem in regard to the specific problem has been reported
 - Payment
 - Renew Certificate

H. Amendments of Registration

- Where changes are proposed to the label or packaging of a registered pesticide, notification of such change shall be made in writing to the Ministry with a copy of the proposed label and where required a photograph of the proposed container.
- Issue new certificate if found legally accepted

I. Re-registration

- If the original applicant of a registered pesticide wishes to change the trade name, formulation, active ingredient concentration or use of the pesticide
- or another person intends to import, formulate, manufacture, pack, repack, distribute, sell or label that pesticide, an application for re-registration shall be submitted to the Ministry

J. Temporary registration

- Where it is ascertained that the pesticide is new manufactured or it is necessary for protecting pests in relation to health sector
- And if the applicant agrees to fulfill Missing information within that time (1 year)
- To be sold or distributed only for the emergency control of pest outbreaks
- Extension can be given for not more than 1 year

K. Suspension and cancellation

Why?

- the registration was secured in violation of law
- withdrawn from the market (notified by manufacturer)
- no longer effective for its intended use;
- Conditions violated
- new facts or an unforeseen change in circumstances which require cancellation

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- the registrant shall be given 60 days to submit a written justification as to why the registration should not be cancelled.
- decision by the Ministry within 30 days of receipt of written justification
- the registration shall be suspended if one of it pending
- Registrant return the certificate of registration if cancelled

L. Re-evaluation of registration

- If there has been a change in the information required to evaluate the pesticide or
- If the procedures needed to properly evaluate the human, animal or plant health hazards, environmental hazards, efficacy or quality of the pesticide or of pesticides of the same class or kind;
- in light of recommendations arising from international fora or international organizations

M. Registry

- a list and information on all registered
- separate central database or archive

N. Fees (Issued by Counsel of Ministers)

- Registration of one product 1000.00 birr**
- Renewal of registration 500.00 birr**
- Importation of pesticide for research 100.00 birr**
- Importation of pesticides for trade 300.00 birr**
- To be involved in the business of pest 100.00 birr**
- List of Registered pesticides 5 birr/page**



O. Arrangements for Registration For Pesticides used in Flower Farms

- The flower industry has grown very fast since it started (now more than 83 exporting and more than 1200 ha green house + open field)
- Very limited list of pesticides (not satisfying the industry)
- The Government made two arrangements to help the industry

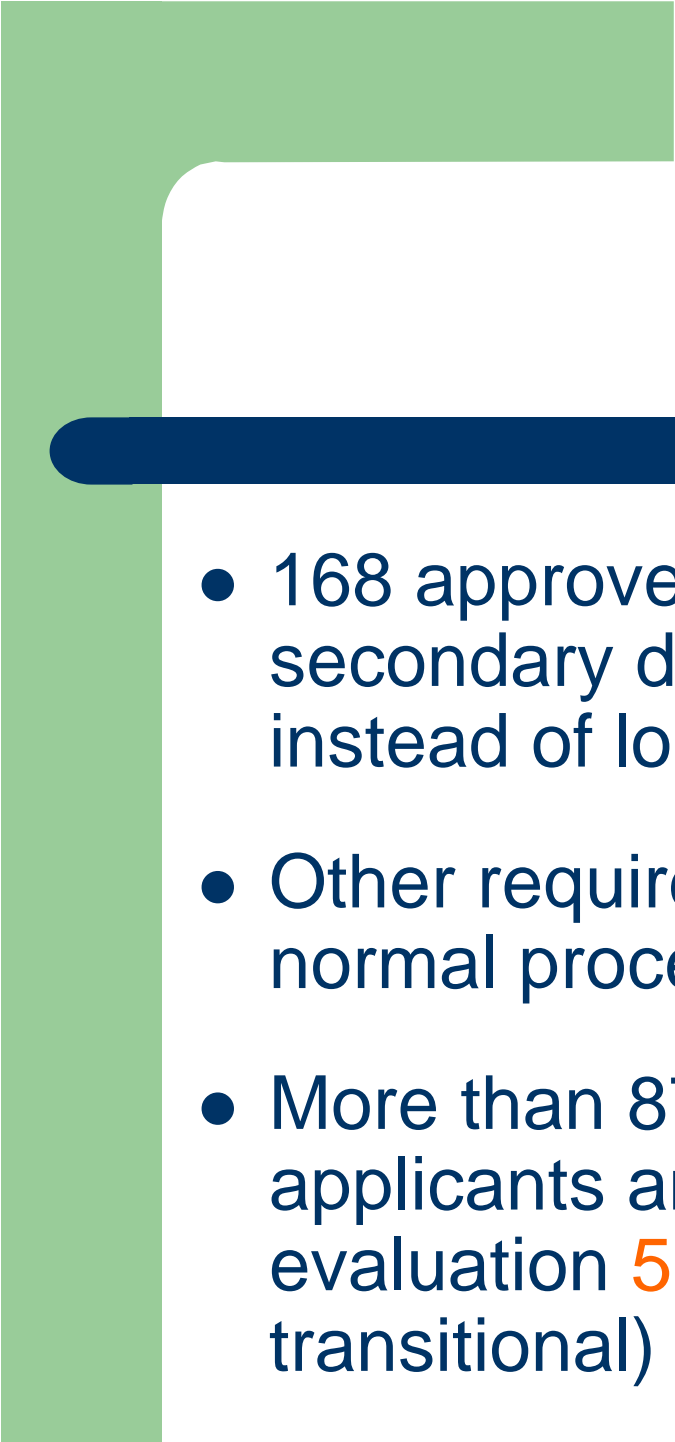

1. Interim arrangement

- Made growers to import only for their farm, controlled by the APHRD, but as this should not continue.

2. Transitional arrangement

- Secondary data for already imported and are being used on flower farms PRC/EIAR collected
- AND those pesticides considered effective were checked for their registration in the
 - MPS Code list 2006/Kenya, Tanzania and Uganda
 - MPS Code list 2006 Holland
 - MPS code list 2005 ETHIOPIA and
 - Kenya Pesticides Registration Booklet 2006

Based on this

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- 168 approved for registration based on secondary data collected from flower farms / instead of local efficacy trial
 - Other requirements are the same with normal procedure.
 - More than 87 dossiers are submitted by applicants and are in the process of evaluation 50% are registered. (still transitional)



P. Challenges in Registration

- Delay of the efficacy trial
- Low Capacity to conduct efficacy trial for flower farms
- Submission of incomplete document by registrants (time)
- Inadequate pesticide laboratory analysis capacity
- Limited staff at APHRD to evaluate dossier

Q. Activities On-going by APHRD in connection to strengthening the pesticide registration system.

PRRP-Ethiopia

- In place since February 2010 with activities to strengthen the capacity of pesticide registration in Ethiopia
- Upgrading the quality control laboratory by the TCP



Thank You!
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ETHIOPIA
