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Pesticide Registration - processes and challenges

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Scope of Presentation

- Commercialising a pesticide in Kenya (East Africa)
- Pesticide Regulations
- Pesticide Registration.

Qualifications to speak

Biological control company based in Kenya

Production and sale of BCAs

BCAs need registration just like other pest controlling agents

Registrations in Kenya, Ethiopia, Ghana, Mozambique and SA

Why register a pest control product

Safety and efficacy

Safety – people (consumer, operator, public), crop, environment, non- target organisms.

Efficacy – does it work, does it do what the label says, consumer protection.

Once registered

Registration is approval by the authorities

Approval to:

Use,

Advertise,

Sell,

Store and

Supply.

Approval terminology

Crop protection

Pest Control Products – hence the Pest Control Products Board in Kenya (PCPB).

Plant Protection Products (PPPs).

Approval – the African situation

Every country is different (nearly)

Differing degrees of transparency.

Need for clarity on:
- what is required,
- interpretation,
- consistency of risk assessment.

Registration process - simplified

Pre-sub consultation (local help)

Submission of application and technical dossier of information

Independent efficacy trials – three seasons

Review of dossier and trials reports and subsequent committee approval – hopefully!

Application form and dossier

FORM A3

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A BIOCHEMICAL PEST CONTROL PRODUCT

Introduction

1. These guidelines are for any proposed use of the chemical products (growth regulators, pheromones, botanical products, e.t.c) of naturally occurring organisms (bacteria, protozoa, fungi, viruses, plants, animals, e.t.c) for the control of invertebrate pests and pathogens of crops and livestock, the control of weeds, public health and environment. **The use of biochemical pest control products for the control of vertebrate pests is not contemplated.**
2. Information in support of a request for registration, both published and unpublished should be supplied in the form of a summary data sheet laid out according to the format given in Form A3
3. A pre-registration consultation between the applicant and the registration authority is strongly recommended.

Application form

Information on the both:
- active ingredient (a. i.), and
- formulated product

Statement made in application form supported in technical dossier

e.g. LD_{50} for rats
Source of independent evidence

Application form

Major component:

- Toxicology and
- Eco-toxicology information.

from independent source.

Cost of registration

Depends on many factors

In the EU this would cost
500,000 - 750,000 USD

In Africa ranges from:
30,000 – 200,000 USD

Cost incurred by the manufacturer/distributor

Time taken for registration

Again variable:

How much information already available?

Ghana - one to two years
Kenya – three to four years

If a GMO then 10 years.

Scope for harmonisation

EU has harmonised approval of active ingredients (a.i. s)

a.i. s go into harmonised list – Annex 1.

Formulated products approved at EU national and zonal level.

No harmonisation in Africa apart from CILLS countries.

Kenya – Case study

Transparent

Process and forms available on www.pcpb.or.ke

Annual published list of registered products.

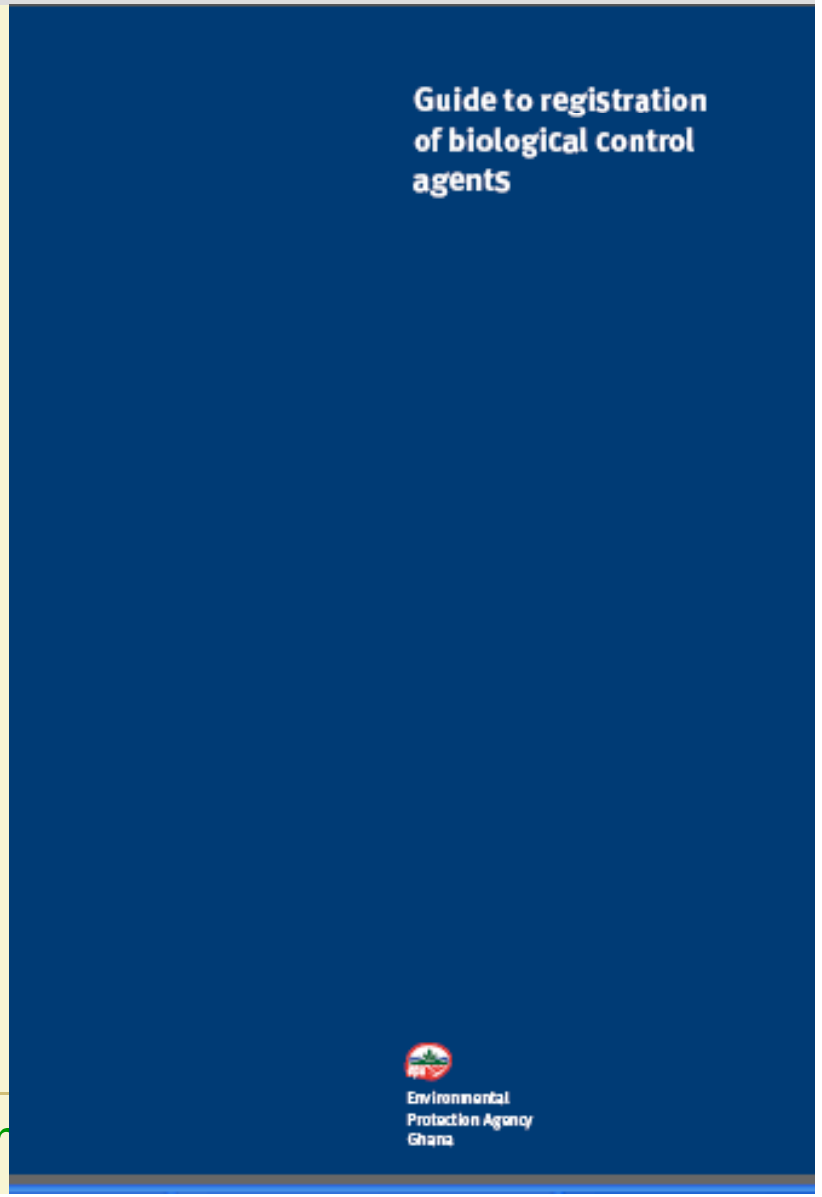
Under resourced and lengthy decision time.

Ghana – Case study

Just published "Guide to registration of biological control agents" in Ghana

Funded by **DFID**'s Research Into Use (**RIU**) programme
www.researchintouse.com

realIPM www.realipr



Botanical pesticides in Europe

Rotenone – withdrawn

Nicotine - withdrawn

Neem (azadirachtin) – never registered/approved

Natural pyrethrins - approved

On farm production

Regulators ignore “on farm” production for home use.

Regulators only activated when sold in market place

Commercialising?

Size of the market - crops, area, target pests.

Cost of bringing to market place?

Registration and marketing costs

Competitive products

Commercialising?

Why will the famer buy our product?

Price – especially important for the small farmer

Efficacy – linked to resistance

Availability – distribution issues

Residues – more for export crops

Commercialising?

Specific or broad spectrum?

Role in an IPM programme?

Shelf life at ambient temperatures

Reliability of production

Consistent Quality

Spider mite		IRAC	WHO class	*Phytoseiulus*		*Amblyseius cucumeris*		*Trichodermma asperellum*	
Trade name	active ingredient			% death	persist (wks)	% death	persist (wks)	% death	persist (wks)
Karate, Tata Umeme	*lambda cyhalothrin*	3A	II	>75%	8-12 wks	>75%	8-12 wks	compatible	zero
Fastac, Bestox,	*alpha cypermethrin*	3A	II	>75%	8-12 wks	>75%	8-12 wks	compatible	zero
Brigade, Talstar,	*bifenthrin*	3A	II	>75%	8-12 wks	>75%	8-12 wks	compatible	zero
Trucer	*spinosad*	5	U	<25%	zero	<25%	zero	compatible	zero
Dynamec,	*abamectin*	6	?	>75%	2 wk	25-50%	5 days	compatible	zero
Milbeknock	*milbemectin*	6	?	>75%	2 wks	25-50%	5 days	compatible	zero
Apollo,	*clofentezine*	10A	U	<25%	zero	<25%	zero	compatible	zero
Nissorun	*hexythiazox*	10A	U	<25%	zero	<25%	zero	compatible	zero
Baroque	*etoxazole*	10B	?	>75%	3 wks	>75%	3 wks	compatible	zero
Tedion,	*tetradifon*	12D	U	<25%	zero	<25%	zero	compatible	zero
Pegasus	*diafenthiuron*	12A	U	>75%	1 wk	<25%	zero	compatible	zero
Torque	*fenbutatin oxide*	12B	U	<25%	zero	<25%	zero	compatible	zero
Peropal	*azocyclotin*	12B	II	<25%	zero	<25%	zero	compatible	zero
Omite	*propargite*	12C	III	>75%	zero	>75%	zero	compatible	zero
Dictator plus	*propargite +*	12C	III	>75%	zero	>75%	zero	compatible	zero
	+tetradifon	12D	U	<25%	zero	<25%	zero	compatible	zero
Secure	*chlorfenapyr*	13	II	>75%	4 wks	>75%	4 wks	compatible	zero
Cascade	*flufenoxuron*	15	U	<25%	zero	<25%	zero	compatible	zero
Mitac,	*amitraz*	19	III	>75%	2-4 wks	>75%	2-4 wks	compatible	zero
Pride, Magister	*fenazaquin*	21A	II	>75%	1 wk	>75%	1 wk	compatible	zero
Mite clean	*pyrimidifen*	21A	III	> 75%	2 wks	> 75%	2 wks	compatible	zero

Commercialising?

Finally:

What will be our return on investment?

What are the risks (do a SWOT)?

Decision time: YES or NO

Conclusion

Regulations are important

Opportunities for harmonisation and regional mutual recognition

Safety is the most important aspect in PPP use

Thank you