Registration and extending the use of PPPs

Pesticide Control Service
Department of Agriculture and Food Laboratories,
Backweston Campus,
Young’s Cross,
Cellbridge,
Co. Kildare.
Pesticide Registration Division

- Regulatory and Enforcement Unit (Coordinators of the evaluation)
- Chemistry Unit: Phys/chem properties, Analytical Methods, Residues
- Toxicology Unit
- Environment Unit
- Efficacy Unit
Pesticide Control Service

Functions

1. Register, or not, plant protection products and other pesticides for marketing and use-

2. Monitor packaging, labelling and selling of Pesticides at Wholesale and Retail Level

3. Monitor the Quality of Pesticides

4. Monitor Residues of Pesticides in Agricultural Produce

5. Review new and existing a.s.’s as part of the EU review programme
Functions

6. Removal of unsafe or ineffective products from the market

7. Permitted products are adequately packaged and labelled

8. Access to more dangerous products is limited to trained operatives (professionals)

9. Advertising and promotion is consistent with proven performance
What are PESTICIDES??

- **Plant Protection Products**
  
  *Definition*
  
  Fungicides
  Herbicides
  Insecticides
  Molluscicides
  Rodenticides
  Etc......

- **Biocidal Products**
  
  *Definition*
  
  Disinfectants / Detergents / soaps
  Preservatives for wood etc..
  Fungicides, rodenticides etc..
  Not used for agricultural purposes.
  Any product not covered by PPP, Veterinary or Cosmetic legislation
Registration and Enforcement legislation

- **Plant Protection Product**
  - Statutory Instrument 83 of 2003

- **Biocides**
  - Statutory Instrument 625 of 2001

- **General (all chemicals)**
  - Statutory Instrument 624 of 2001
Other Legislation


• **Council Directive 76/769/EEC**
  SI 220 of 2003 (Limitations Directive)

**Poisons (Prohibitions of the use of Certain Substances for Agricultural Purposes)**
Regualtions 1991
  SI 361 of 1991
“The Product”
PRECAUTIONS
HARMFUL TO AQUATIC ORGANISMS.
DO NOT CONTAMINATE PONDS, WATERWAYS OR DITCHES WITH CHEMICAL OR USED CONTAINER.
WASH CONCENTRATE FROM SKIN OR EYES IMMEDIATELY.
WASH HANDS AND EXPOSED SKIN BEFORE EATING, DRINKING OR SMOKING AND AFTER WORK.
KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.
KEEP OUT OF THE REACH OF CHILDREN.
KEEP IN ORIGINAL CONTAINER, TIGHTLY CLOSED IN A SAFE PLACE.
WASH OUT CONTAINER THOROUGHLY, EMPTY WASHINGS INTO SPRAY TANK AND DISPOSE OF SAFELY.
DO NOT RE-USE CONTAINER FOR ANY PURPOSE.

STORAGE
STORE WELL AWAY FROM SEEDS, FERTILISERS AND ANIMAL FEEDINGSTUFFS IN A SAFE, DRY PLACE DESIGNATED AS AN AGROCHEMICAL STORE.

PROTECT FROM FROST

1 litre e
A suspension concentrate containing 400 g/l (37.4 % w/w) pyrimethanil.

Risk and safety Information
HARMFUL TO AQUATIC ORGANISMS, MAY CAUSE LONG TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT.

THIS MATERIAL AND ITS CONTAINER MUST BE DISPOSED OF IN A SAFE WAY.

Supplied by:
BASF Ireland Limited,
Bracstown Business Park,
Clonea,
County Waterford
Tel: 01 825 5701
Fax: 01 825 5238

Manufactured by:
BASF Aktiengesellschaft,
67056, Ludwigshafen, Germany
Authorization Holder:
BASF plc, P O Box 4,
Earl Road, Chesterfield,
Derbyshire, S36 0GQ

Emergencies (24 hour):- Tel 0044 101 485 8222

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PRODUCT
SCALA SC

• Active substance (Pyrimethanil 37.4%)
• Co formulant
  Stabilisers (XXXXXX 10%)
  Wetters (XXXXXXXXX 3%)
  Spreaders (XXXXXXXXX)
  Solvents (XXXXXX 10%)
  Carriers (China clay)
  Safeners (XXXXXXXX)
Product Registration

• The Active Substance is reviewed at EU level

• The product is reviewed at MS level
EU REVIEW PROCESS

• The Active Substance is evaluated at EU level by one Member State.
• The products containing that Active Substance are then reviewed by each Member State.
• e.g., Glyphosate reviewed by German authorities. RoundUp, Pride, Touchdown, Gallup etc.. Being reviewed by PCS and our equivalent in all Member States.
• 4 Stages
• New active substances
New AS or Existing AS in Review

- Dossier on both active substance and product
- Studies on:
  - Physical and Chemical properties
  - Mammalian toxicology
  - Environmental fate & behaviour
  - Eco-toxicology
  - Efficacy
  - Residue levels at harvest etc..
Typical Active Substance dossier 50-100 folders
PESTICIDE REGISTRATION

Product registered if acceptable –

- Risk to Human health
  - User/worker
  - Bystander
  - Consumer

- Risk to the environment
  - Soil
  - Water
  - Air
  - Non-target species

- Efficacy
But …..

Product with unacceptable risk will **not** be registered ……..

……. regardless of biological performance in pest control (Efficacy) or other needs or interests
Annex II
Dossier for a full authorisation of an a.s., and a PPP.
All of these folders will have to be analysed and summarised by PCS staff.
Active Substance & Product Dossiers

• 30-100 folders made up of studies, study summaries and risk assessments.

• €200 million + to bring this active substance to market.

• Target major crops first (wheat, potato etc..)
Active Substance & Product Dossiers

• Target big use countries (FR, UK, DE)
• Registration costs
• Company collaboration with 3rd parties
Problems from your side

Lack of Products

“Lack of tools in the tool box”

Competition from abroad
Lack of Products

- **Problems from our side**
  1) Size of Market
  2) Data provision (protection)
  3) Efficacy / Residue
  4) Cost of registration
  5) Similar problems in most countries
  6) Sorry to say, things could get worse!!!
# Fungicides for Use in Strawberries April 2006

**IRELAND**
- Azoxystrobin
- Carbendazim
- Chlorothalonil
- Captan
- Tolyfluanid
- Propamocarb
- Iprodione
- Fenarimol
- Pyrimethanil
- Myclobutanil
- Fenhexamid
- Sulphur

**UK**
- Iprodione
- Fosetyl aluminium
- Chlorothalonil
- Captan
- Myclobutanil
- Sulphur
- Propamocarb
- Dinocap
- Kresoxim methyl
- Carbendazim
- Bupirimate
- Copper oxychloride +
- Metalaxyl
- Fenarimol
- Boscalid +
- Pyraclostrobin
- Fenhexamid
- Tolyfluanid
- Pyrimethanil

**Off label**
- Azoxystrobin
- Fenpropimorph
- Quinoxyfen

Pesticide Control Service
## Herbicides for Use in Strawberry April 2006

### IRELAND
- Trifluralin
- Isoxaben
- Propyzamide
- Napropamide
- Clopyralid
- Simazine
- Cycloxydim
- Fluazifop-P-Butyl
- Paraquat
- CIPC
- Phenmedipham
- Glufosinate ammonium
- Sethoxydim

### UK
- Trifluralin
- Isoxaben
- Chlorthal-dimethyl
- Propachlor
- Propyzamide
- Napropamide
- Clopyralid
- Simazine
- Cycloxydim
- Fluazifop-P-Butyl
- Lenacil
- Pendimethalin
- Paraquat
- CIPC
- Phenmedipham
- Glufosinate ammonium

### Off Label
- Asulam
- Ethofumesate

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## Insecticides for Use in Strawberry

**April 2006**

### IRELAND

- Cypermethrin
- Pirimicarb
- Dimethoate
- Carbofuran
- Chlorpyrifos
- Malathion
- Trichlorfon N/A
- Oxdemeton methyl
- Bifenthrin
- Methiocarb
- Metaldehyde

### UK

#### Off Label

- Ferric phosphate
- Pirimicarb
- Chlorpyrifos
- Methiocarb
- Tebufenpyrad
- Chloropicrin
- Bifenthrin
- Fatty Acids
- Nicotine
- Aluminium ammonium phosphate
- Bacillus thuringiensis
- 1,3 dichloropropene
- Fenbutatin oxide

#### Off Label

- Clofentazine
- Pymetrozine
- Spinosad
- Abamectin
- Thiacloprid
- Spiromesifan

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**Pesticide Control Service**
Extend the use (REGISTER ADDITIONAL USE)

- Amistar registered in 1996 for use in cereals, in 2006 Amistar has 27 different crop uses (13 off label approvals).

- Calypso (Thiacloprid) registered in 2005 on 1 use (apples) but now has 5 off label approvals
Entend the Use
What do we need?

• Label approval
  – Efficacy data
  – Plant Residue and metabolism data

• Off label approval
  – Plant Residue and metabolism data

Is the company interested in spending money (€30-50,000) on a smaller crop? (No, not yet)

Grower organisations in other countries will spend this money and produce the data eg. HDC in UK
COST €€€€

- 4 Residue trials required for a minor crop. (raspberries)
- 8 Residue trials required for a major crop (wheat)

- Residue trial €4-7,000 each
- Efficacy €2-3,000 each
DATA PROTECTION

• Grower group in a MS that produces data are entitled to reserve this data for their use only. e.g., HDC in UK produce residue data on a crop/product.

Other MS must negotiate access to thios HDC data or produce data of its own....
# Current position in Ireland PPP

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<tr>
<th></th>
<th>2001</th>
<th>2002</th>
<th>2005</th>
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<tbody>
<tr>
<td>Amateur PPPs</td>
<td>203</td>
<td>185</td>
<td>187</td>
</tr>
<tr>
<td>Professional PPPs</td>
<td>1116</td>
<td>768</td>
<td>738</td>
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<tr>
<td>Combination PPPs</td>
<td>21</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Total registered PPPs</td>
<td>1340</td>
<td>966</td>
<td>934</td>
</tr>
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Pesticide Control Service

- Website address:
  www.pcs.agriculture.gov.ie
- Pesticide Legislation
- Pesticide Registrations
- Application forms
- Up to date information
- See our 2006 Handbook
- E-mail: pcs@agriculture.gov.ie
- gordon.rennick@agriculture.gov.ie
- Phone 01-6157618 (direct line)