

# **Registration and extending the use of PPPs**

**Gordon Rennick B.Agr.Sc., M.Sc.**

Pesticide Control Service

Department of Agriculture and Food Laboratories,

Backweston Campus,

Young's Cross,

Cellbridge,

Co. Kildare.



# **Pesticide Control Service**

**Pesticide  
Residue  
Division**

**Pesticide  
Registration  
Division**

**Pesticide Control Service**



# 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**

**Pesticide Control Service**



# **Pesticide Control Service**

## **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**
  - **Council Directive 91/414/EEC**
  - **Statutory Instrument 83 of 2003**
- **Biocides**
  - **Council Directive 98/8/EC**
  - **Statutory Instrument 625 of 2001**
- **General (all chemicals)**
  - **Council Directive 99/45/EC**
  - **Statutory Instrument 624 of 2001**





# Other Legislation

- **Council Directive 79/117/EEC**

SI 320 of 1981, 237 of 1985, 342 of 1987 and 339 of 1990(Prohibitions Directive)

- **Council Directive 76/769/EEC**

SI 220 of 2003(Limitations Directive)

## **Poisons (Prohibitions of the use of Certain Substances for Agricultural Purposes) Regulations 1991**

SI 361 of 1991





# **“The Product”**



# BASF

## 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



® = Registered trade mark of BASF

810019311E001444

# Scala®

**For the control of leaf scab in apples  
and grey mould in strawberries.**

## 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,  
Bracktown Business Park,  
Clonsilla,  
County Meath  
Tel: 01 825 5701  
Fax: 01 825 2038

Manufactured by:  
BASF Aktiengesellschaft,  
67056, Ludwigshafen, Germany  
Authorization Holder:  
BASF plc, P.O. Box 4,  
Earl Road, Cheshire Hulme,  
Cheshire, SK8 6JG

Emergencies (24 hour):- Tel 0044 161 485 6222

PCS No.: 01178

To avoid risks to man and the environment, comply with the instructions  
for use



# **PRODUCT**

## **SCALA SC**

- **Active substance (Pyrimethanil 37.4%)**
- **Co formulants**
  - 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





# PESTICIDE REGISTRATION

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 3<sup>rd</sup> 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  
Quinoxifen





# 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**



# Insecticides for Use in Strawberry

## April 2006

### IRELAND

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

### Off Label Thiacloprid

### UK

- 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





# **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





# **Extend 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

	<u>2001</u>	<u>2002</u>	<u>2005</u>
• Amateur PPPs	203	185	187
• Professional PPPs	1116	768	738
• Combination PPPs	21	13	9
• <b>Total registered PPPs</b>	<b>1340</b>	<b>966</b>	<b>934</b>





# Pesticide Control Service

- Website address:

**[www.pcs.agriculture.gov.ie](http://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](mailto:pcs@agriculture.gov.ie)**
- **[gordon.rennick@agriculture.gov.ie](mailto:gordon.rennick@agriculture.gov.ie)**
- **Phone 01-6157618 (direct line)**

