



PESTICIDE REGULATION

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Pesticide Safety Directorate





Outline

- Introduction
- Role and aims of the Pesticides Safety Directorate
- Pesticide regulation
- Product labels
- Future developments
- Useful sources of information

Introduction

- Environment branch; Environmental fate and behaviour, ecotoxicology and efficacy
- Evaluate data for submissions under COPR and PPPR.
- Supply agronomic advice to PSD, Defra and other stakeholders.
- Provide advice to applicants on data requirements for approval of products and uses.

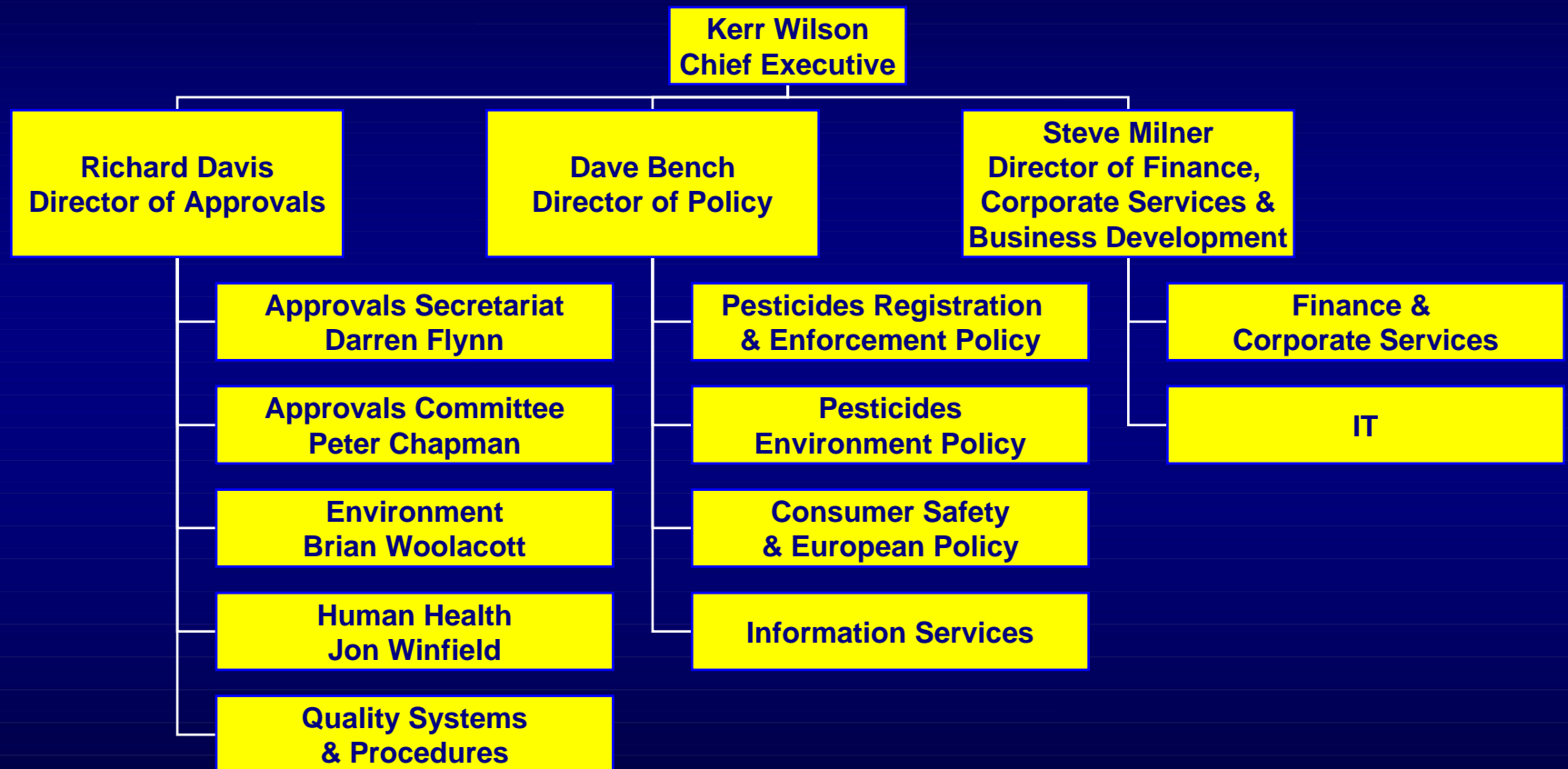
PSD's role

- Provides controls on pesticides used in agricultural, horticultural and in the home/garden.
- Monitors the use of pesticides and takes enforcement action against illegal use.
- Provides policy advice to Ministers and take the lead on pesticide issues for Defra.
- Supports the reviews of the safety of pesticides on the market.
- Aims to standardise pesticide regulation within Europe.
- Co-ordinates pesticide Research & Development.
- Supports the UK and EU reviews of the safety of pesticides on the market.

PSD's Aims

- Our aims are to:
 - ensure the safe use of pesticides for people and the environment
 - reduce the negative impacts of pesticides, encourage reductions in their use, taking account of best practice, and the development and introduction of alternative ways to control pests, weeds and diseases. This is part of the move towards sustainable food and farming.
 - harmonise pesticide regulation within Europe and provide a level playing field for crop protection.

PSD's Structure





Pesticide Regulation

Pesticide Legislation

- The Food and Environment Protection Act 1985 (FEPA) (Part III)
- The Control of Pesticides Regulations 1986 (COPR) as amended by the Control of Pesticides (Amendment) Regulations 1997
- The Plant Protection Products Regulations 1995 (PPPR)

FEPA

- FEPA provides statutory powers to control pesticides. Four overall aims:
 - *To protect the health of human beings, creatures and plants*
 - *To safeguard the environment*
 - *To secure safe, efficient and humane methods of controlling pests*
 - *To make information about pesticides available to the public.*

COPR

- The mechanism by which these aims are to be achieved is set out in regulations made under the Act.
- The Control of Pesticides Regulations 1986 (COPR) as amended by the Control of Pesticides (Amendment) Regulations 1997

COPR continued

- Under the terms of the *COPR* (as amended), only approved products can be sold, supplied, stored, advertised or used.
- It is an offence to use non-approved products or to use approved products in a manner that does not comply with the statutory conditions of use, including where the crop or situation is the subject of an off-label extension of use.

COPR continued

- Approvals under COPR relate only to products containing active ingredients on the market by 25 July 1993. Products containing newer active ingredients, or older ingredients subsequently listed in Annex I to EC Directive 91/414/EEC, will be granted approval under Plant Protection Products Regulations.

EC Directive 91/414


- EC Directive 91/414/EEC (The 'Authorisations' Directive);
 - EC Directive 91/414/EEC is intended to harmonise arrangements for the authorisation of plant protection products within the European Community.

Directive 91/414/EEC

- Concerning the placing of Plant Protection Products on the Market
 - Annex I - the listing of the active substance.
 - Annex II - the evaluation of the active substance data.
 - Annex III - the evaluation of the formulated product data.
 - Annex IV & V – standard risk phrases and safety precautions.
 - Annex VI – Uniform Principles – what and how.

Plant Protection Products Regulations 1995 (PPPR)

- In the UK, 91/414 is implemented through the *Plant Protection Products Regulations 1995 (PPPR)* – under which all agricultural and horticultural pesticides will eventually be regulated;
 - *The Plant Protection Products Regulations 1995 (as amended by various Plant Protection Products (Amendments) Regulations (PPPR), and*
 - *The Plant Protection Products (Basic Conditions) Regulations 1997 (PPP(BC)R)*



Plant Protection Products Regulations (PPPR) 1995

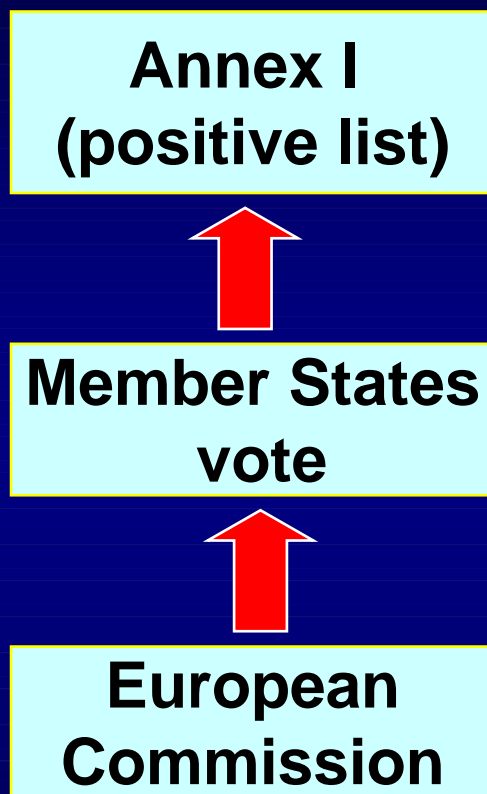
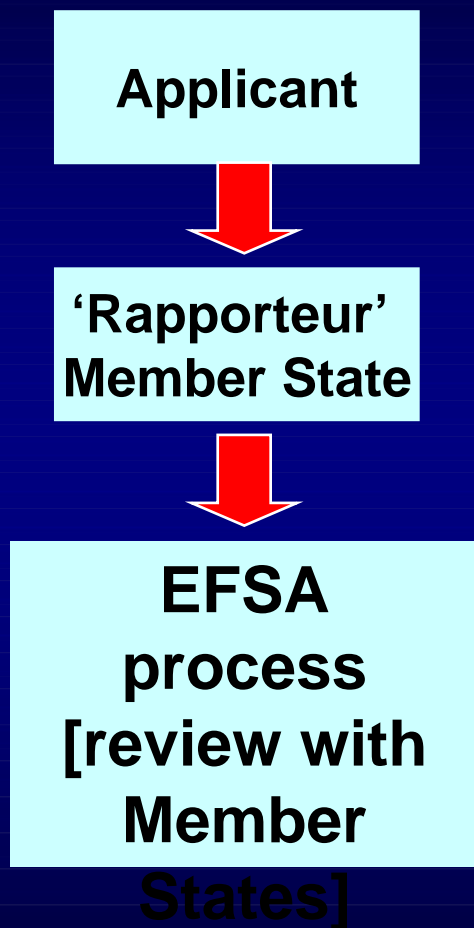
- Initially only applied to actives new to EU
- All other new products still under COPR
- EC Review programme: in place by 2003
 - to assess dossiers for all existing actives
 - to produce a positive list of a.s. (Annex 1)
 - MS to 're-register' all products containing Annex 1 listed actives

Active substance

Product (re-)registration

Risk assessment

Risk management



EC Review programme: progress List 1 and 2

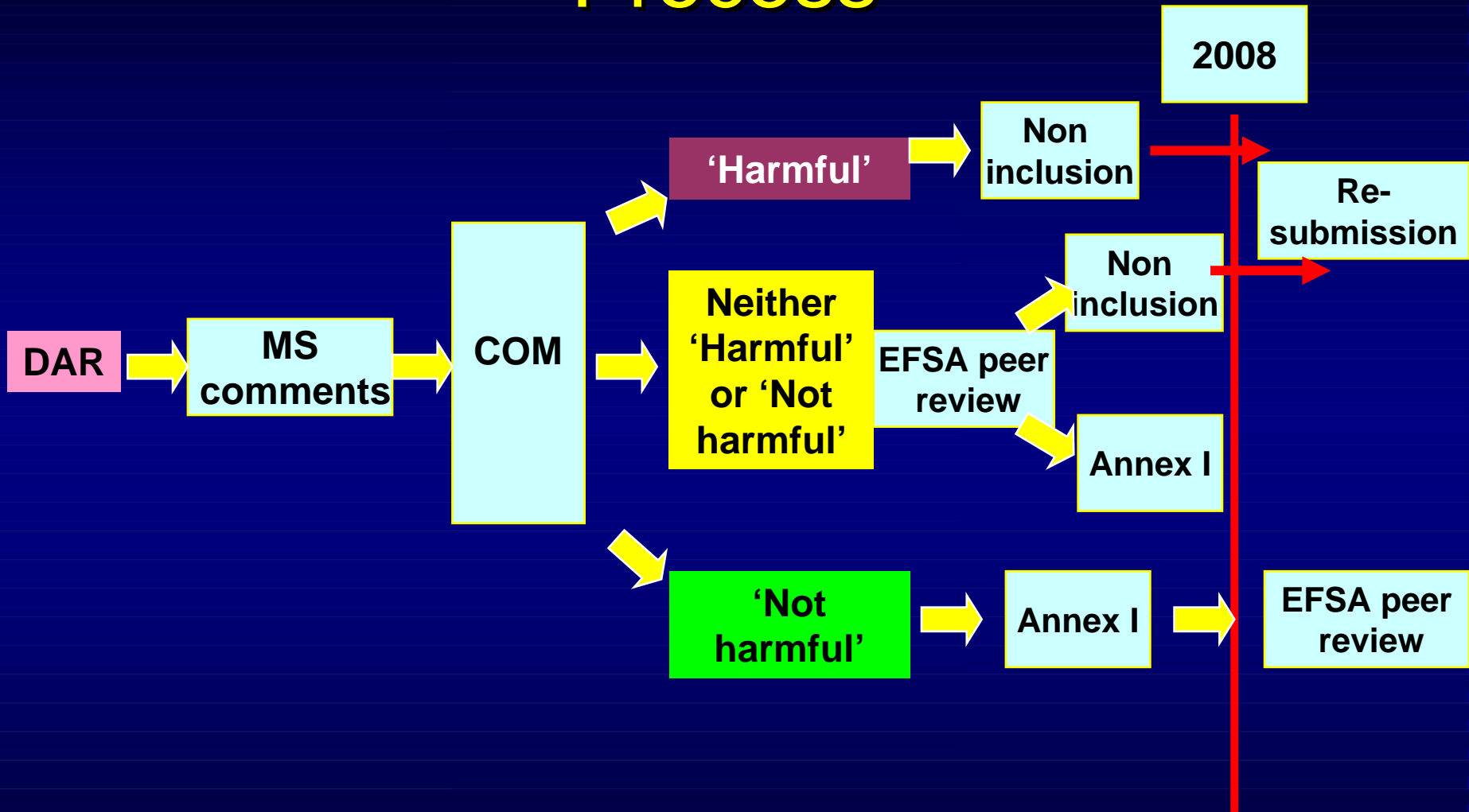
- List 1 – 90 dossiers submitted by Aug 1993
- List 2 – 63 dossiers submitted by Dec 2000
- Deadline: 31st December 2005:
 - achieved for decisions on the 1st and 2nd stage review substances

EC Review programme: progress

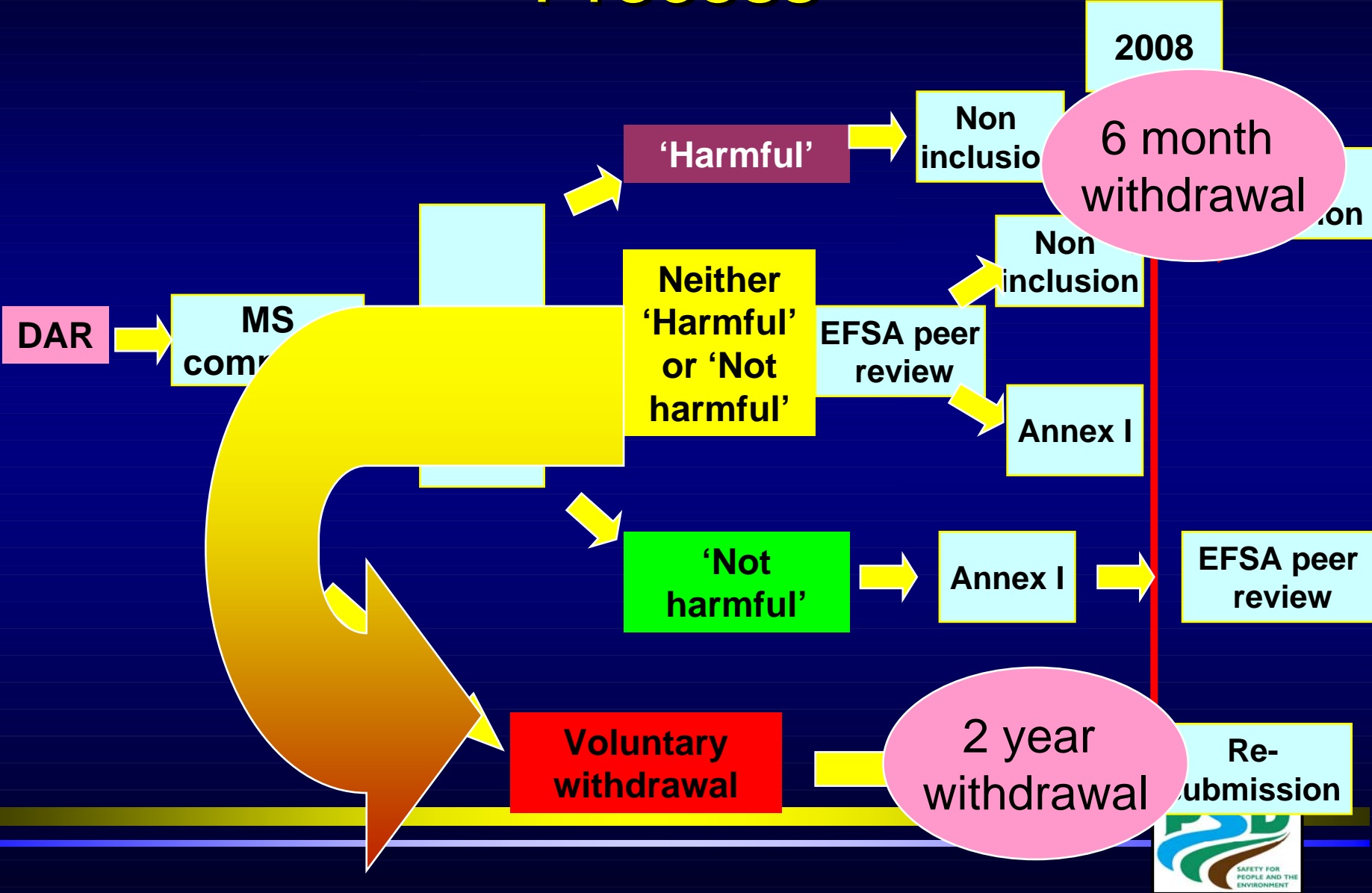
List 3 and 4

- List 3 – 163 dossiers submitted by Dec 2004
- List 4 – 198 dossiers ongoing
(includes micro-organisms, plant extracts and commodity substances)
- Deadline: 31st December 2008. All submissions **and decisions** on all List 3 and 4 substances must be made by Dec 2008 !
- To facilitate this some active substances have been voluntarily withdrawn (amending Regulation 1095/2007) e.g. asulam.

Process



Process



Product labels

Regulation of product labels

- Approval for the sale, supply, storage, advertisement and use of pesticides is governed by COPR or PPPR.
- The safe, humane and efficacious use of pesticides is enabled by;
 - the general conditions on sale, supply, storage, advertisement and use of **all** pesticides (as set out in the Regulations)
 - specific conditions in the product approval (which set the requirements for the label text)
 - other guidance for the end-user such as the ‘Code of Practice for the Safe Use of Pesticide on Farms and Holdings’.

Regulation of product labels

- The general ‘conditions of sale and supply’ that apply to all products, state that:
 - “No person shall sell, supply or otherwise market to an end user an approved pesticide [plant protection product] other than in the container which has been supplied for that purpose by the approval holder and labelled in a manner consistent with the approval.”

Regulation of product labels

- The product specific ‘condition of sale and supply’ on the final Notice of Approval specifies that:
 - the product must be supplied with ‘Approved Text’ in line with that on a referenced draft label text (as submitted by the applicant and used in PSD’s evaluation) and amended in line with any amendments specified on the Notice of Approval.

What must a label contain?

- Product Identity
- Important information area (replaces statutory area)
- Safety information
- Directions for use

The top 3 must appear on the visible part of the label

Statutory Area: Example

COMPLIANCE WITH THE FOLLOWING CONDITIONS OF USE AND ALL SAFETY PRECAUTIONS MARKED * IS A LEGAL REQUIREMENT

FOR USE ONLY AS AN AGRICULTURAL/HORTICULTURAL/INDUSTRIAL HERBICIDE

Crops: Wheat (winter), barley (winter), oilseed rape, strawberry,
natural surfaces not intended to bear vegetation

Maximum individual dose: }

Maximum number of treatments: }

Maximum total dose: }

Latest time of application: }

Other specific restrictions: }

Full details are given in Statutory Area
on attached leaflet

READ ALL OTHER SAFETY PRECAUTIONS AND DIRECTIONS FOR USE BEFORE USE

Important Information area

IMPORTANT INFORMATION

FOR USE ONLY AS AN AGRICULTURAL HERBICIDE

Crops:	Winter wheat, winter barley and oilseed rape
Maximum individual dose:	Winter wheat and barley: 2 litres product/ha Oilseed rape: 1 litre product/ha
Maximum number of treatments:	Winter wheat and barley: 2 per crop
Maximum total dose:	Oilseed rape: 3 litres product/ha/crop
Latest time of application:	Winter wheat and barley: Before second node detectable stage Oilseed rape: 14 days before harvest
Other specific restrictions:	This product must not be used on durum wheat

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS



ARAMO®

MAPP 10280

An emulsifiable concentrate containing 50 g/litre (5.3% w/w) tepraloxymid for use in winter oilseed rape (including industrial oilseed rape), sugar beet, fodder beet, peas, winter and spring field beans, cabbage, cauliflower, linseed (including industrial linseed), flax, carrots, bulb onions, leeks and green cover on land temporarily removed from production e.g. set-aside.

The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work

Pack size 1 to 10 litres

SAFETY PRECAUTIONS

Precautions marked * are a legal requirement

Operator protection

*Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

* WEAR SUITABLE PROTECTIVE GLOVES when handling the concentrate.

*However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

WASH CONCENTRATE from skin or eyes immediately.

WASH HANDS AND EXPOSED SKIN before meals and after work.

WHEN USING DO NOT EAT, DRINK OR SMOKE.

Aramo must only be applied via conventional ground sprayer, not via knapsack sprayers.

Environmental protection

Do not contaminate surface waters or ditches with chemical or used container.

Storage and disposal

KEEP IN ORIGINAL CONTAINER, tightly closed in a safe place.

Keep dry and frostproof in a suitable pesticide store.

RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of safely.

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.

KEEP OUT OF REACH OF CHILDREN.

Medical advice

IF SWALLOWED, DO NOT INDUCE VOMITING: seek medical advice immediately and show this container or label.

BASF plc

Agricultural Division

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Batch number

Transport regulations

No longer relevant.

Statutory conditions of use or storage are no longer signposted

This label is compliant with the CPA Voluntary Initiative Guidance





Anticholinesterase Compounds

PSD require the following additional phrase to be included after the name of the active substance on the main area of the container label:

(active substance) is an anticholinesterase organophosphate [or carbamate]. Handle with care.

Transitional Arrangements

A period of 3 years will therefore be allowed for newly formatted labels to be placed on the market

Directions of Use

- Information needed to use the product safely and effectively.
- Standard format and layout
- Logical, consistent and clear
- Statement on status

Label statement

- 'IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.
- Must appear on all labels for professional products.

Basic format

- Restrictions and warnings
- Doses and pests controlled
- Crop information
- Following crop information
- Mixing and application information
- Compatibilities

Company Advisory Information

- Aid clarity
- Provide additional information
- Supports the approved text
- Is not required as a condition of sale or supply
- Does not need to be supported by data
- Does not contradict the approved text or conditions of approval

Examples

- Could include:
 - Calibration information
 - Nozzle details
 - Pest information
 - Good Agricultural Practice

Future Developments

Future Developments

- EU review of pesticides
- Proposed regulation on PPP
- Sustainable Use Directive

EU review of pesticides

Phase	Number of substances	Not Supported	Supported and awaiting decision	Inclusion in Annex I (to date)	Non inclusion in Annex I (to date)
1	90 (74)	-	-	59 (57)	31 (17)
2	148(44)	98 (8)	-	31 (28)	19(8)
3	387(163)	251(69)	116 (76)	20(18)	0
4	329(36)	203 (6)	126 (30)	0	0
Total	954(317)	552 (83)	242 (106)	110 (103)	50 (25)
New substances					
	143(64)		53(13)	81(51)	9

Number of substances with UK approvals when the review started given in **brackets**

March 2008



Proposed Regulation on PPP

- Introduction of new 'hazard triggers' to eliminate active substances based on their intrinsic properties rather than their risks in use. This would have a major impact on product availability.
- Zonal mutual recognition
 - Applies to products
 - 3 zones (except protected uses)
 - MS can impose additional risk mitigation for workers and bystanders

Proposed Regulation on PPP

- Comparative assessment and substitution
 - Identify candidates based on hazard criteria
 - MS must verify that there are sufficient, effective, alternatives.
- Improved environmental protection
 - Biodiversity.
 - Review of products which may breach standards laid down in the Water Framework Directive.
- Avoidance of animal testing

Sustainable Use Directive

- Framework to promote 'best practice':
 - national action plans to reduce the risk from, and dependence on, pesticides;
 - application equipment tested within 5 years;
 - training and certification of spray operators, distributors and advisors within 2 years;
 - ban (subject to derogations) aerial spraying;
 - protect the aquatic environment including more extensive and flexible use of buffer zones;
 - minimise use in public spaces and special conservation areas;
 - minimising the risk of pollution through handling, storage and disposal;
 - promote Integrated Pest Management (IPM); and
 - monitor progress through the calculation of risk indicators.

More Information

- The Pesticides Safety Directorate
 - www.pesticides.gov.uk
 - Codes of Practice
 - Labelling handbook
 - Latest news on EU review
 - Proposed regulation on PPP
 - Sustainable Use Directive