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Workshop on efficacy requirements and evaluation of plant protection products based on low-risk active substances

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UK Biopesticides scheme

- DEFRA more biopesticides and sustainable use

- In response to very few UK products;

    -Regulation and costs seen as a barrier, including efficacy

UK Biopesticides Scheme' launched 1st April 2006

- Four categories:
  - Semiochemicals – pheromones, mass trapping
  - Micro-organisms (bacterium, fungi, protozoa, virus)
  - natural plant extracts
  - 'other' novel products on case by case basis

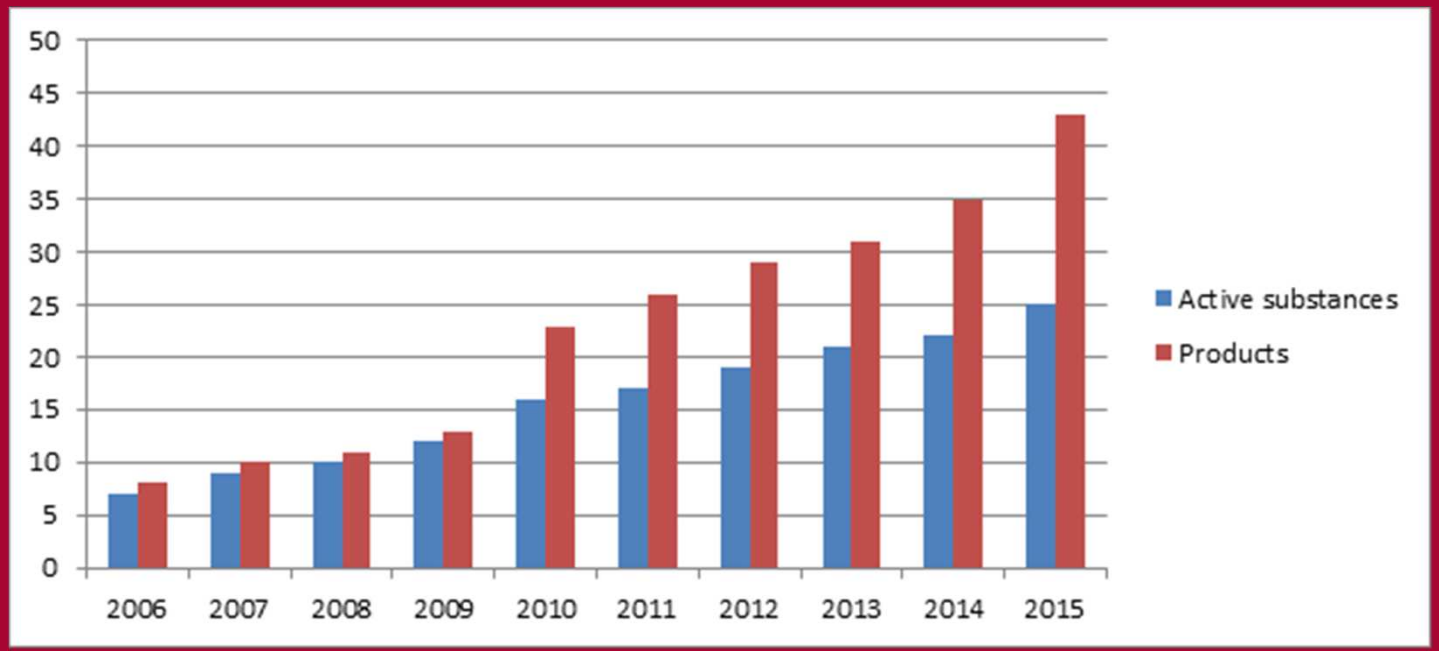



UK Biopesticides scheme-operation

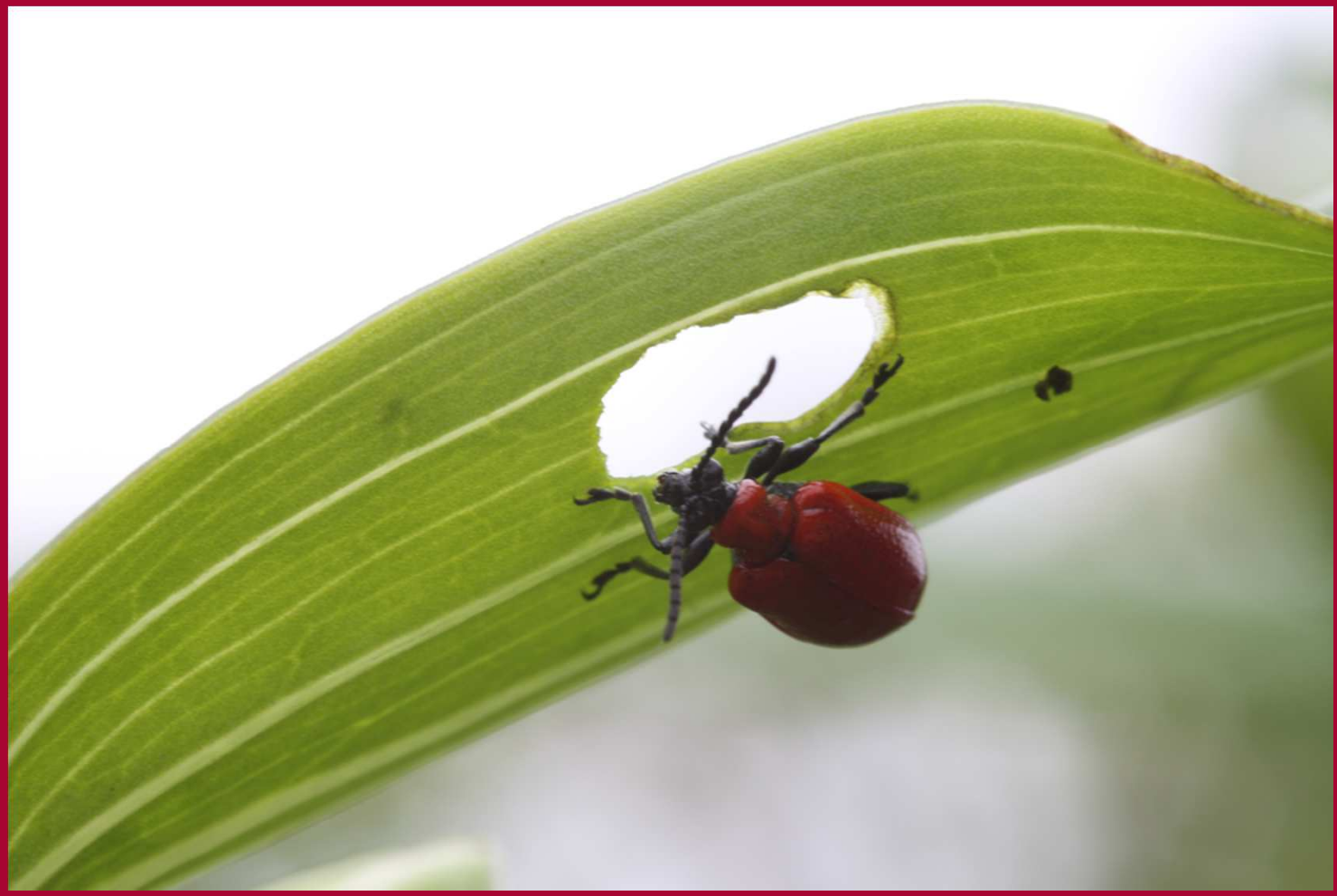
- Policy driver – Sustainable Use Directive
- Work within EU framework
- Apply minimum requirements
- Develop efficacy guidance in conjunction with industry (EPPO PP1/276(1): Principles of efficacy evaluation for microbial plant protection products. EPPO PP 1/264 (1) Mating disruption pheromones.)

Additional outcomes from UK Biopesticide scheme

- Reduced fees
- Biopesticide ‘champion’ to act as contact point
- Encouraged pre-submission meetings early in process
- Formed IBMA/Efficacy working group



Efficacy assessment of Biopesticides



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Preliminary data

1. Background information- published papers

2.Laboratory based research,

3. Screening data,

4. Small scale trials.

5. Explains mode of action

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Preliminary data

6. Rationale for trials

7. Dose justification.

8. Reduces number of field trials

9. Resistance

10. Assists in deriving label instructions and optimising performance

Minimum Effective Dose

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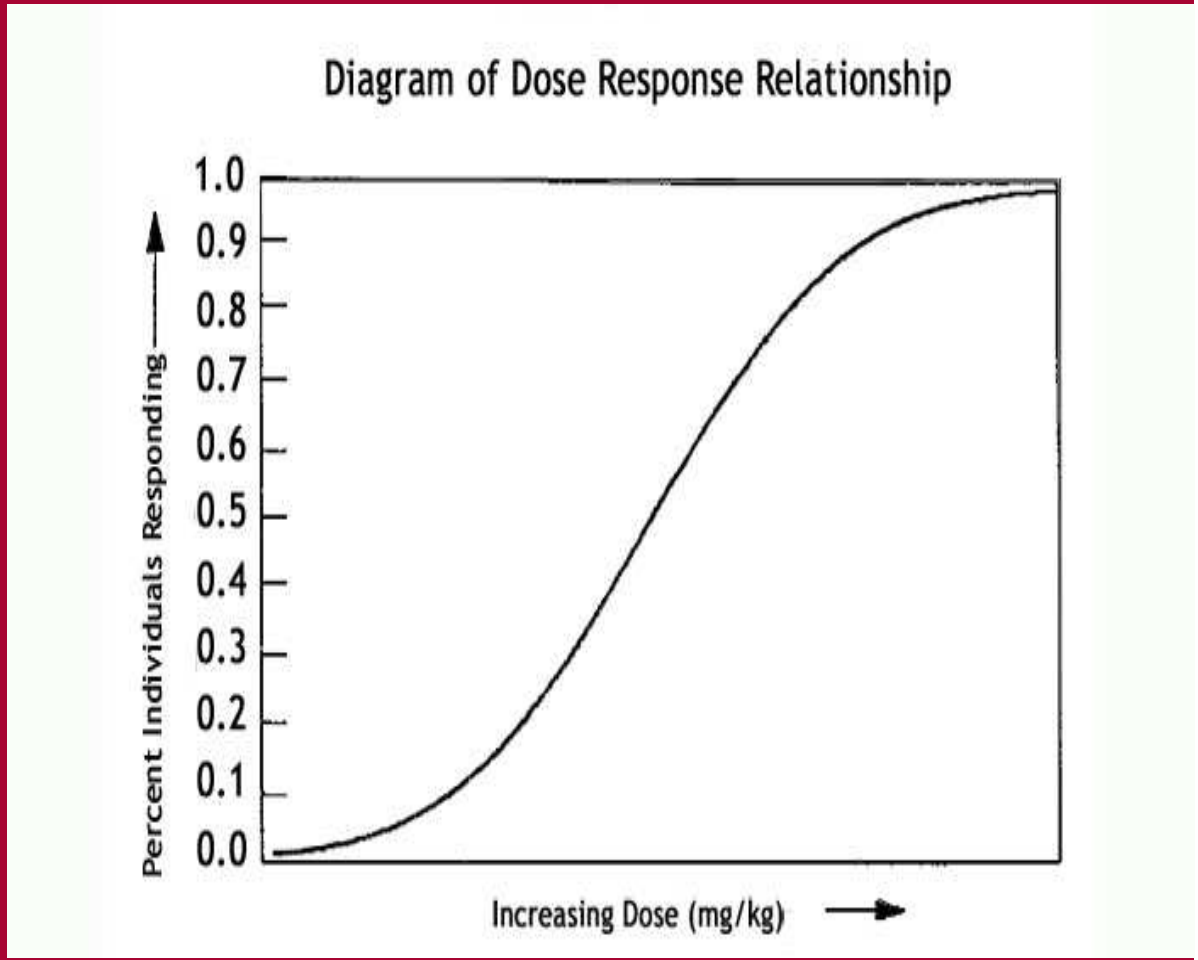
1. Preliminary and effectiveness trials can support MED.

2. UK accept variability.

3. Provide justification for the dose.

4. Mode of action – e.g. pheromone



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Effectiveness

1. Use of EPPO guidelines; Legitimate to adapt when there are gaps, justify adaptation.
2. Where no guidance, explain methodology
3. All uses of a product must be supported by data, usually a mixture of preliminary and field/glasshouse trials.
4. Use EPPO minor use extrapolation tables
5. GEP for field work (UK specific category).

Biggest problem – poorly explained MOA and assessment of trials; poor, unsupported label instructions

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Relevance of EPPO standards

EPPO PP1/276(1): Principles of efficacy evaluation for microbial plant protection products.

EPPO PP 1/264 (1) Mating disruption pheromones

DEFINING VALUE/BENEFIT

EPPO Principles of Acceptable Efficacy (1/214 (3))

- Significantly superior to the untreated control i.e. the use is better than no use
- Performance same order as standard
- BUT several characteristics of product performance may justify lower efficacy levels

EPPO Principles of Acceptable Efficacy (1/214 (3))

e.g.

- Broader range of crop/target growth stages
- More robust to climate or soil type differences
- Compatibility with other plant protection measures
- Lower resistance risk
- Fewer undesirable side effects

UK Label differentiation

Effect	Label claim
Over 80%	Control
60-80%	Useful/moderate/partial
Between 40-60%	Some control/reduction in damage
Below 40%	Claims permissible provided demonstrable benefit

UK Label differentiation of claims

ADVANTAGES

Can be applied to any type of pesticides

Can account for variability, provided there is a benefit

Allows growers to understand expected performance

DISADVANTAGES

Has to be case by case

Depends on type of economic impact pest has (e.g. 50% control may be acceptable in some cases but not others

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Crop safety trials

HSE

Preliminary data

Effectiveness trials - observations can support crop safety of active and formulation

No dedicated crop safety trials (unless a herbicide)

Addresses other areas by reasoned case e.g. succeeding/adjacent crops

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Taint (242) and Transformation (243)

Taint : Provide reasoned case, following EPPO, or label warning

Transformation: Reasoned case – no residues, Preliminary data – biological activity on transformation

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Resistance

IRAC ‘***The most effective strategy to combat insecticide resistance is to do everything possible to prevent it occurring in the first place***’**.**

1. Metabolic resistance
2. Target-site resistance
3. Penetration resistance
4. Behavioural resistance

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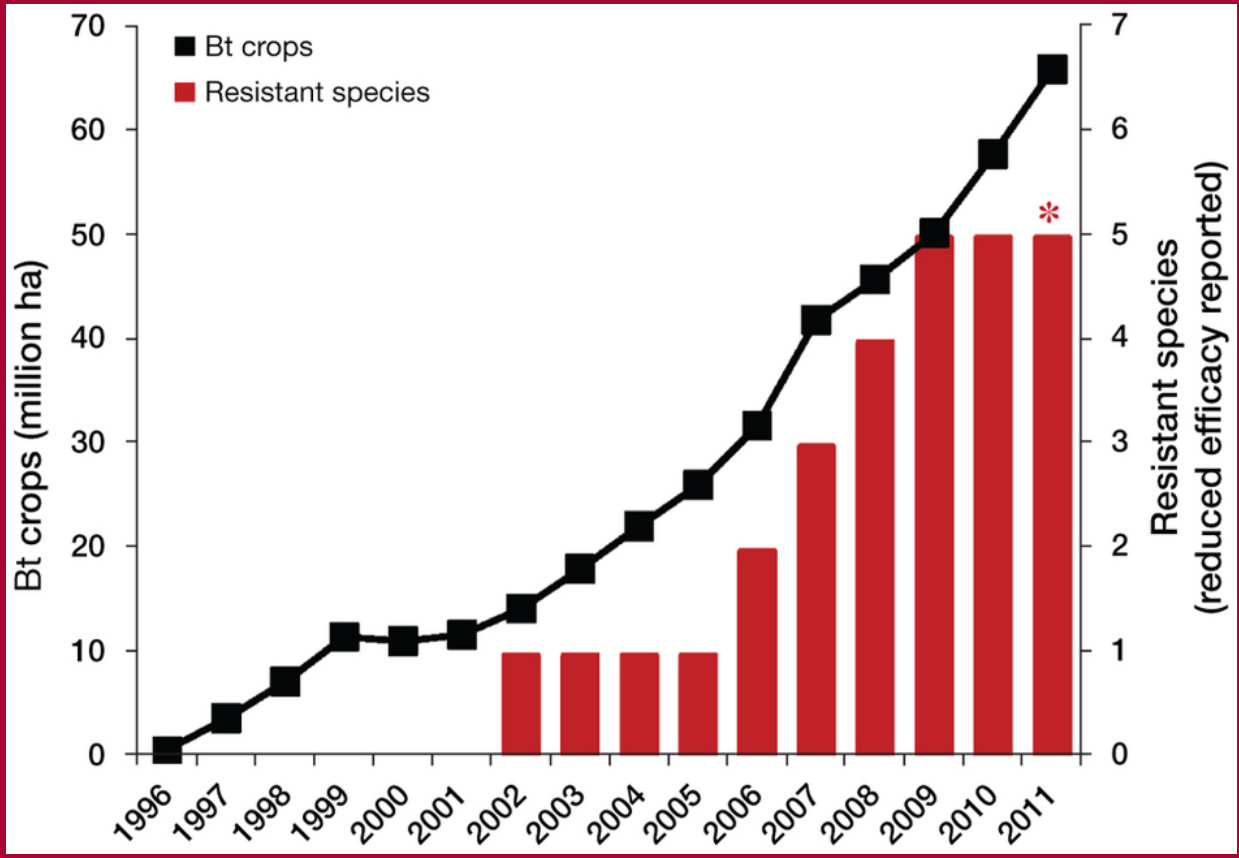
Resistance

Resistance is associated with the frequency of applying pesticides and dosage used (rate response).



Nature Biotechnology 31, 510–521 (2013)

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Resistance and UK Labelling

Poorly addressed by applicants and MS

'*this is a low risk and no resistance*' -not acceptable

Follow EPPO 1/213, based on MOA and why low risk

Resistance strategy for UK – limit number of applications for UK – need to establish; per generation, per crop, per glasshouse structure, spot spraying

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Resistance and UK Labelling

Resistance – e.g. XXXX has not been reported to have any insect resistance. However, it is good practice to use such products as components of Integrated Pest Management systems, alternating with other control measures.

Conclusions

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1. Working within data requirements, reasoned cases. preliminary studies can reduce actual data.

2. EPPO forms framework for Efficacy requirements.

3. Develop more specific standards.

4. Resistance management needs greater consideration and MS harmonisation.

5. Appropriate label wording for optimum use.

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Discussion points for workshop:

-Resistance management needs greater consideration and MS harmonisation

-Better use of applicants knowledge in submissions

-Better worded labels to optimise performance

-Future requirements for proportionate efficacy

- Greater use of development work
- GEP or grower trials
- Better use Mutual recognition?