

The UK Biopesticide Scheme

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Overview

- UK Pilot scheme
- Challenges of the scheme
- Lessons learned
- Biopesticide scheme details
- Future

Reasons for UK Pilot Project for 'biologicals'

- Concern over the lack of alternative control options especially biologicals

Reasons:

- Market size
- Regulatory requirements and associated fees considered inhibitory to market development

UK Pilot Project for 'biologicals'

- Introduced June 2003
- Aim to increase availability in UK
 - Better understanding of requirements
 - And how to meet them
 - Offer pre- submission meetings
 - Reduce fees
- PSD to develop expertise in this area

Challenges of the pilot scheme

- Reaching out to non-traditional 'customer'
 - IBMA
 - Academic/research
- Offering support at early stages in development
- Fee structure and success rate dependent on quality of submission

PSD's Pilot Scheme success

- Approved three products under the Pilot Scheme
- Other biologicals were at various stages of evaluation
- Several pre-submission meetings held

Lessons learned

Pre-submission support and liaison with PSD is essential!

- Agreeing in advance what needs doing prior to submission can avoid the generation of unnecessary data
- Applicants encouraged to provide good general information (what it is, mode of action, background levels)

More lessons learned

- Need to ensure awareness of regulatory process and data requirements at the outset. e.g. GLP, areas of risk assessment
- There is scope for pragmatism and flexibility in the data requirements
- Use public domain data and appropriate cases – explain relevance
- Ensure arguments are consistent across specialist area

Lessons learned – evaluation (1)

- Completeness check should examine supporting information and cases in reasonable detail
- Beneficial to draft the biological properties of the DAR in the early stages of evaluation

Lessons learned – evaluation (2)

- Beneficial to hold interim meeting of specialist evaluators
- Applicant to justify which published paper relevant to which Annex point
- Assessments for one product may be used to inform the future assessment of other similar products/novel applications

Biopesticide Scheme (1)

- 'Bio-pesticides Scheme' launched 1st April 2006
- Four categories:
 - Semiochemicals
 - Micro-organisms (bacterium, fungi, protozoa, virus)
 - natural plant extracts
 - 'other' novel products on case by case basis

Biopesticide Scheme (2)

- Fees
 - £22,500 biological/plant extracts
 - £13,500 semiochemicals
 - plus £ 7,500 for EU consideration (Annex I listing)
- Assigned Biopesticide ‘champion’ to act as contact point for general enquiries

Biopesticide Scheme (3)

- Free pre-submission support and advice on the registration process and data requirements
 - Ideally early in product development wherever possible e.g. prior to any efficacy trials programme
- Internal biopesticides e-mail group to keep awareness of current issues and disseminate information

Approved UK Biopesticide Products

Active substance	Trade name (Target)
<i>Bacillus thuringiensis</i>	Dipel F (caterpillars)
<i>Verticillium lecanii</i>	Mycotal (whitefly) Vertalec (aphids)
<i>Phlebotomus gigantea</i>	PG Suspension
8,10-dodecadien-1-ol	Exosex CM (codling moth)
<i>Coniothorium minutans</i>	Contans WG (Scerotinia)
Zucchini Yellow Mosaic Virus (ZYMV – weak strain)	Curbit (ZYMV)
<i>Cydia pomonella virus</i>	Cyd-x (codling moth)
<i>Candida oleophila strain O</i>	Nexy 1 (grey and blue mould)

3 approved
1985-2003

5 approved
2004- 2007

Future

- Continue to identify opportunities to establish contacts with researchers and industry
- Continue to play an active part in relevant EU/OECD initiatives
- Develop Biopesticide area on psd website

and finally...

For more information visit: www.pesticides.gov.uk



The screenshot shows the PSD website homepage. At the top left is the PSD logo. Below it is a navigation bar with 'User Areas' and several menu items: Main, PSD Databases, Applicant advice, Farmers & growers, Amenity users, Home garden, Food industry, Biopesticides, and Advisory groups. The 'Biopesticides' link is circled in white. Below the navigation bar is a sidebar with 'In this section' and 'Useful links'. The main content area shows a breadcrumb trail 'You are in: PSD home » PSD Home Page', a welcome message, and a 'Getting started' section with six links, each accompanied by a small image: 'What does PSD do?' (field), 'What are pesticides?' (insect), 'How we approve pesticides for use' (sunflowers), 'How we ensure pesticides are used safely' (field), 'Making sure our food is safe' (pumpkins), and 'Minimising the environmental impact of pesticides' (insect).

Or

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