

Experience with the UK pilot scheme and consequences for the Biopesticide scheme

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REBECA workshop: Review of potential risks
of botanicals & semiochemicals
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Overview

- UK Pilot scheme
- Challenges of the scheme
- Lessons learned
- Biopesticide scheme launched April 2006
- Future developments

Reasons for UK Pilot Project for 'biologicals'

- Concern over the lack of alternative control options especially biologicals.
- 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
 - pre- submission meetings
 - Reduced fees
- PSD to develop expertise in this area

Challenges

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

PSD's Pilot Scheme success

- Codlemone – ‘Exosex CM’
- ZYMV (Zucchini Yellow Mosaic Virus – weak strain) – ‘Curbit’
- Fungal agent for control of Sclerotinia - ‘Contans WG’
- Other biologicals at various stages of evaluation
- Several pre-submission meetings held

Lessons learned (1)

- **Pre-submission support and liaison with PSD is essential!**
- Establish contacts (Confidence)
- Applicants encouraged to provide good general information (what it is, mode of action, background levels)

Lessons learned (2)

- Need to ensure awareness of regulatory process and data requirements at the outset. e.g. GLP, areas of risk assessment
- Use public domain data and appropriate cases – explain relevance
- Ensure arguments are consistent across specialist area
- Encourage applicants to keep initial applications simple

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)

- Pilot scheme completed
- Launch '**Bio-pesticides Scheme**' 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
 - 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

Future

- Biopesticides - dedicated area on PSD website (link from home page)
- Continue to identify opportunities to establish contacts with researchers and industry (e.g. links with DEFRA research funding, field trials visits, visits to manufacturers)