

# **OECD Biopesticide Expert Seminar (28-29<sup>th</sup> June 2021)**

## **Efficacy assessment of biopesticide and supporting Label claims: UK perspective**

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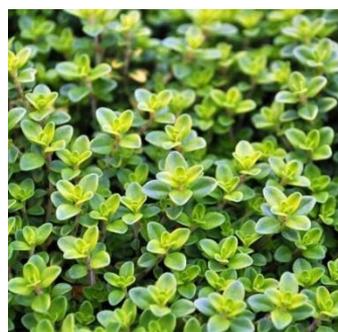
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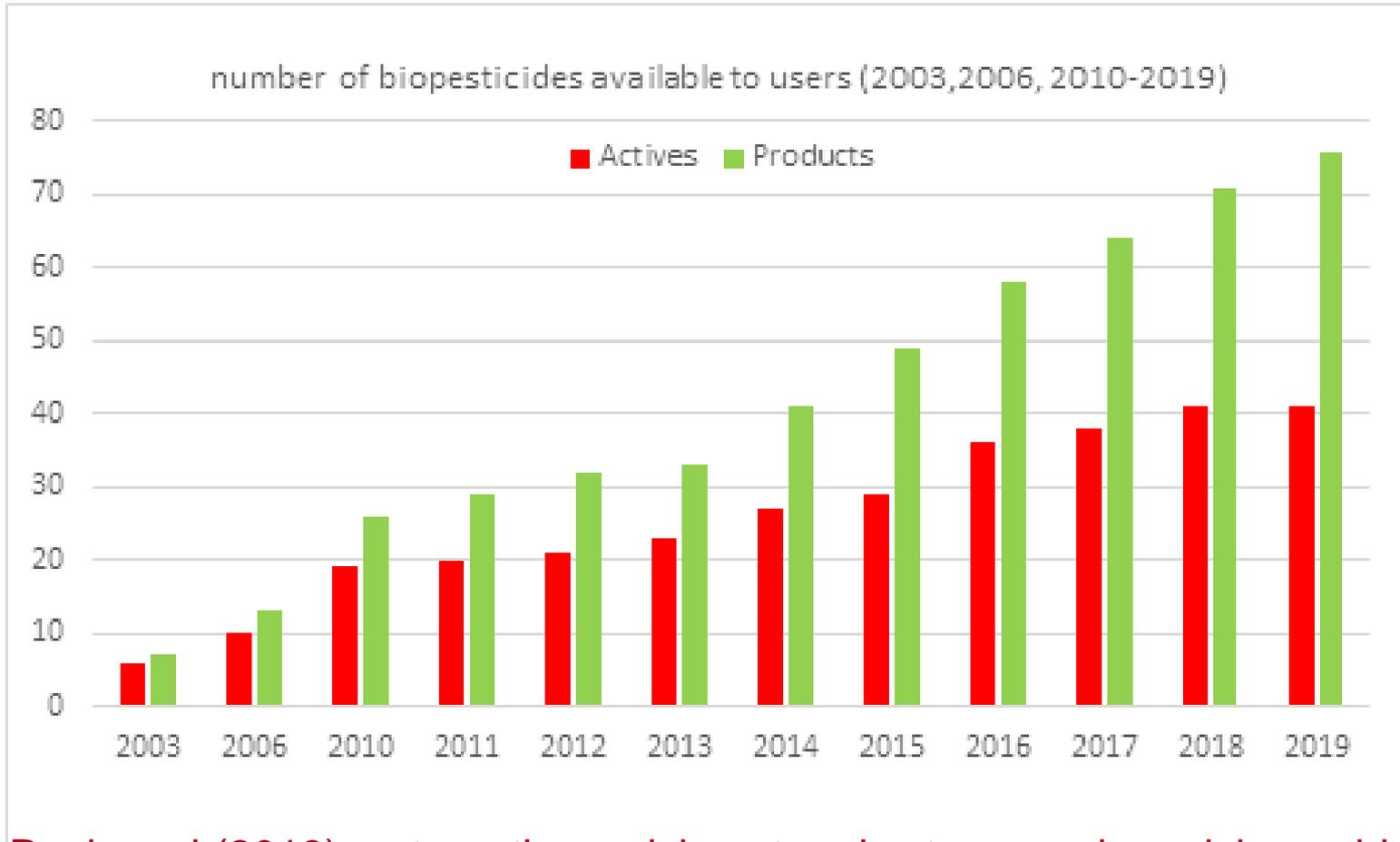


# UK Biopesticides Scheme

- DEFRA Policy (sustainable use) promote biopesticides
  - UK had very few products, with regulation and costs seen as barrier
- Pilot scheme (2003) with reduced fees
- Biopesticide scheme (2006): Semiochemicals, Micro-organisms, natural plant extracts, 'other' novel)



# UK Authorised Biopesticides



- Reviewed (2013) – strengthen advice at early stage, and provision guidance
- Currently considering comments on biopesticides as part of UK consultation on the National Action Plan

# Early Experience of biopesticide scheme



- Established efficacy working group with UK-IBMA:
  - value of efficacy (rather than '*let market decide*'), supporting product labels/growers
  - familiarity with EPPO, identifying guidance
  - Use of public domain data/reasoned cases
  - Understand mode of action, trials methodology
- Good Experimental Practice (Efficacy trials)
  - Encourage Official recognition
  - UK introduced specific 'biopesticide' category

# Pilot Biopesticide scheme: Mating disruption product for Codling moth in orchards



- Challenges for Trials methodology and interpretation of data: un-replicated large plots; monitoring ('trap shut-down'); type of assessments; site history/map
- Importance published information
- UK Efficacy Guideline 220 (2006): Data requirements and trials design for mating disruption pheromone products
  - Number of aspects relevant to other semiochemicals
- Drafted EPPO PP 1/264 (2008) 'Principles of efficacy evaluation for mating disruption pheromones'
  - EPPO PP 312, 324 (Lepidoptera in fruit)

# Importance of Guidance and role of EPPO



- Worked with IBMA to draft EPPO 1/276 'Principles of efficacy evaluation for microbial PPP' (2012)
- Develop confidence with industry that EPPO standards and principles were important, and through engagement could deliver relevant guidance
- EPPO EWG formed: two 'Principles' standards
  - Low Risk (1/296); Plant Defence Inducers (1/316)
- EPPO Minor Use Extrapolation Tables

# EPPO Guidance: Biopesticide or Low risk?



- ‘Low risk’ - both biopesticide/conventional chemicals
- Microbial Biopesticide actives that do not meet ‘low risk’
  - PP 1/276 – Microbial plant protection products
- Efficacy requirements and approach similar for both:
  - Explain mode of action,
  - Use preliminary data, published studies
  - Reduce number of field trials (no specific number given)
  - Reasoned cases in lieu of data
  - Extrapolation approaches

# Efficacy assessment of Biopesticides



# Efficacy data requirements

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- Preliminary data/information
- Effectiveness (including dose justification)
- Resistance

Areas addressed by observations in effectiveness trials and/or reasoned case

- Crop safety (phytotoxicity, yield)
- Unintended side effects (succeeding and adjacent crops; impact in IPM)

# Effectiveness: Supporting Use 1/296



- Number of environmental/ agronomic factors will impact biopesticides
  - Including temperature, humidity, soil/leaf moisture, edaphic
- Need to determine the conditions to perform optimally (e.g. survive, compete, reproduce, colonise, infect)
- Variable performance can be supported, if understand factors impact efficacy
- Communication with growers on product labels



# Preliminary Data



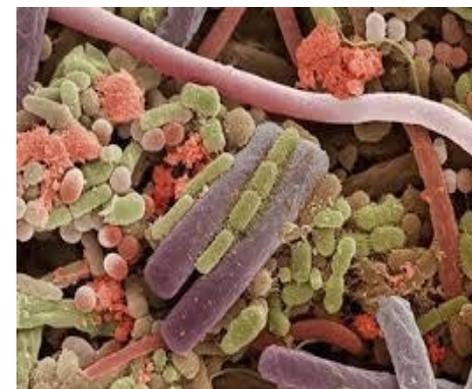
- Published papers (relevance)
- Laboratory based studies
- Detection Screening data
- Glasshouse studies
- Small scale trials
- Non-GEP
- Particularly important for biopesticides, in understanding mode of action, and reducing the number of field trials



# Mode of action – central argument for risk assessment



- Provide consistent argument/case for all areas of risk assessment
- How do applied levels compare to natural
- What happens in the environment
- Persistence
- Are toxins produced
- Host specificity - targets
- Can the organism infect native wild species (plants/organisms) or humans
- Formulation (viability, growth, application, storage)

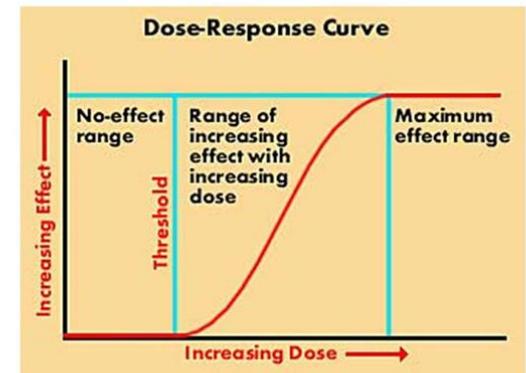


# Preliminary data supporting Dose justification



- EPPO 1/296: demonstrating beneficial effect of proposed dose may suffice, with appropriate explanation (rather than field trials)
- Botanicals – possible to take a similar approach to conventional chemicals (include lower doses in some field trials)
- Microbials, semiochemicals – mode of action means concept less relevant and/or difficult to detect differences in field trials
- **Provide a rationale for the selected dose, reference to preliminary data/information can be very helpful**

The Dose Response Curve



# Efficacy Trials Design



- Mode of action
- Results of preliminary studies
- Published literature
- Biology of the pest/crop
- Relevant EPPO standards (possible to adapt)
- Choice of reference product
- Test under range of conditions
- How the product will be used in practice
- Useful to include some trials based on integrated programmes with conventional chemistry
- **CRD provide free advice on biopesticide trials protocols**



# Presentation/assessment of data



- Understand mode of action and trials design
- Explain variability
- Summarise data appropriately to reflect proposed GAP and label uses
- Wider recommendations and advice to optimise efficacy and highlight any limitations/restrictions



# Common problems



- Trial conduct and/or assessments
  - Timing
  - Interval between applications
  - Testing in a range of conditions
- Applicant knowledge not always reflected in dossiers
- Data grouped together at too 'high' level
- Proposed label does not reflect data
- Inexperience in developing label and understanding what information grower needs

# EPPO 1/214: Principles of acceptable efficacy



- **Primary:** the product should show a benefit that is significantly superior to the untreated. Level of benefit that justifies use depends on impact of target
- **Secondary:** product performance should be comparable to the (commercial) standard. BUT other factors justify authorisation with lower levels:
  - Improved crop safety
  - wider pest spectrum; wider pest or crop stages
  - IPM compatibility
  - resistance management
- **Many of above factors relevant for biopesticides**

# UK Differential Label Claims (fungicide/insecticide)

<u>Effect</u>	<u>Label claim</u>
Over 80%	Control
60-80%	Useful/moderate/partial
Between 40-60%	Some control/reduction in damage
Below 40%	Claims <u>might</u> be permissible

(Herbicides – similar scheme)

- No common minimum level of efficacy, case by case
- Accounts for variability, provided there is a benefit
- Allows growers to understand expected performance

# UK Label Claims - Biopesticides

- Biopesticides - may adapt to wording:
  - *‘Reduces damage caused by .....’*
  - *‘Contributes to the control of..... as part of an integrated program’*
- CRD looking to develop more appropriate to reflect biopesticide modes of action
- EPPO EWG labelling

# Resistance (EPPO 1/296)



- Biopesticides often have multiple modes of action
  - Significantly reduces/slows any resistance
  - but does not completely eliminate
- Used predominantly in protected situations
  - high risk targets, multiple generations
  - Multi cropping situations
  - Often require high number of applications
- Chemical active substances significantly decreased, development and commercial use biopesticides increasing



# Proactive Resistance Management



- Integrate use within range of other control measures
- Consider number of applications per crop/ year in protected situations glasshouse
- Consider blocks of treatments, alternating MoA
- Sustainable use
- Example text: *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*

# Relevant Biopesticide MoA

**IRAC**  
New  
biologicals  
category  
introduced

## Group 11: Microbial disruptors of insect midgut

[ Includes transgenic crops expressing *Bacillus thuringiensis* toxins (however, specific guidance for resistance management of transgenic crops is not based on rotation of modes of action) ]

Different *B.t.* products that target different insect orders may be used together without compromising their resistance management.

Rotation between certain specific *B.t.* microbial products may provide resistance management benefits for some pests. Consult product-specific recommendations.

\* Where there are differences among the specific receptors within the midguts of target insects, transgenic crops containing certain combinations of these proteins provide resistance management benefits.

*Bacillus thuringiensis* and the insecticidal proteins produced  
*B.t. israelensis*, *B.t. aizawai*, *B.t. kurstaki*, *B.t. tenebrionis*

Bt crop proteins \*

Cry1Ab, Cry1Ac, Cry1Fa, Cry1A.105, Cry2Ab, Vip3A,  
mCry3A, Cry3Ab, Cry 3Bb, Cry34Ab1/Cry35Ab1

11A *Bacillus thuringiensis*

*Bacillus sphaericus*

11B  
*Bacillus sphaericus*

**FRAC**

## F6: microbial disruptors of pathogen cell membranes

# 44 Microbial (*Bacillus* sp.)

*Bacillus* sp. and  
the fungicidal lipopeptides produced

*Bacillus*  
*amyloliquefaciens*  
(synonym *B. subtilis*)

strains:

QST 713

FZB24

MBI600

D747

**HSE now require known MoA group to be added to labels**

# UK-Resistance Action Groups



Agrochemical industry, independent organisations, including public-sector research institutes, growers, agronomists, and CRD

[Fungicide resistance action group](#) (FRAG-UK)



[Weed resistance action group](#) (WRAG-UK)



[Insecticide resistance action group](#) (IRAG-UK)



# SUMMARY

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- Biopesticides increasingly important role
- Understanding mode of action
- Efficacy is critical to optimising product performance, explaining variability, and developing recommendations, and supporting other areas of risk assessment
- Product labels - main communication 'tool' for growers
- Using sustainably in integrated programmes
- EPPO, industry and regulators continue to develop guidance
- Early engagement and support for applicants