Health and Safety
Executive

HSE

Biopesticide dossiers: An Ecotoxicology perspective

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Overview

- Feel free to ask questions during talk
- Points raised are opinion i.e. not necessarily shared with all member states/EFSA
- Diverse field ‘Case by case’- not always possible to give definitive ‘answers’
- Will focus on key areas for micro-organisms; including considerations when developing a testing strategy
- Botanicals
- Guidance documents

Active substance submission: where to start?

- Unlike schemes for chemicals there is no clear linear risk assessment scheme for a lower tier assessment…
- Data requirements may not be applicable but need consideration…
- Cases/waivers possible but must be supported
- Next few slides will include some considerations before devising a ‘testing strategy’

Active substance submission Literature review

- Should be conducted in-line with EFSA guidance document (EFSA 2011;9(2):2092)
- Consider taxonomy- any changes to name?
- Relevant publications should be submitted and summarised in dossier

Exposure and proposed GAP of product

- GAP appropriate e.g. is over 100 applications needed?
- Exposure to all (or any) non-target organisms likely?
- If protected use consideration may be required
- EFSA 2014;12(3):3615 protected structure guidance- noting caveats regarding exposure modelling and ‘worst case’ for biologicals



Exposure: micro-organisms background levels and survival

- Discuss with fate colleagues- micro-organisms- is it likely populations will be within natural levels following application?
- Likely survival in aquatic and soil compartments?
- Whilst difficult requires ‘sufficient’ information to support claims e.g. literature studies

Micro-organism: strains and ‘Read across’

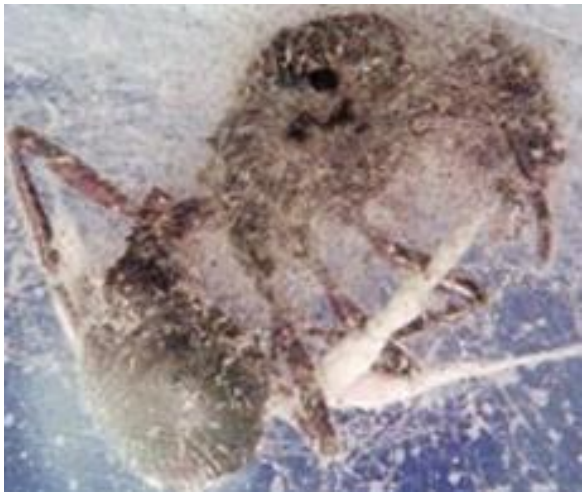
- Consider species data available and whether correct strain has been tested
- May be possible to read across from other strains
- If studies are required they should test specific strain, not just species.
- *No specific studies on micro-organism strain XX have been conducted. Data for other strains are presented in the table below for the risk assessment.*
- ‘Bridging data’? Other consideration?

Which non-target organisms are likely to be exposed?

- Which non-target organism groups are applicable to substance? (mode of action, specificity etc)
- ‘Sufficient’ information available to conduct a qualitative assessment?
- consider previous slides- literature studies, ‘read-across’ exposure etc)
- Background levels should be put into ‘context’
- If consideration is required…

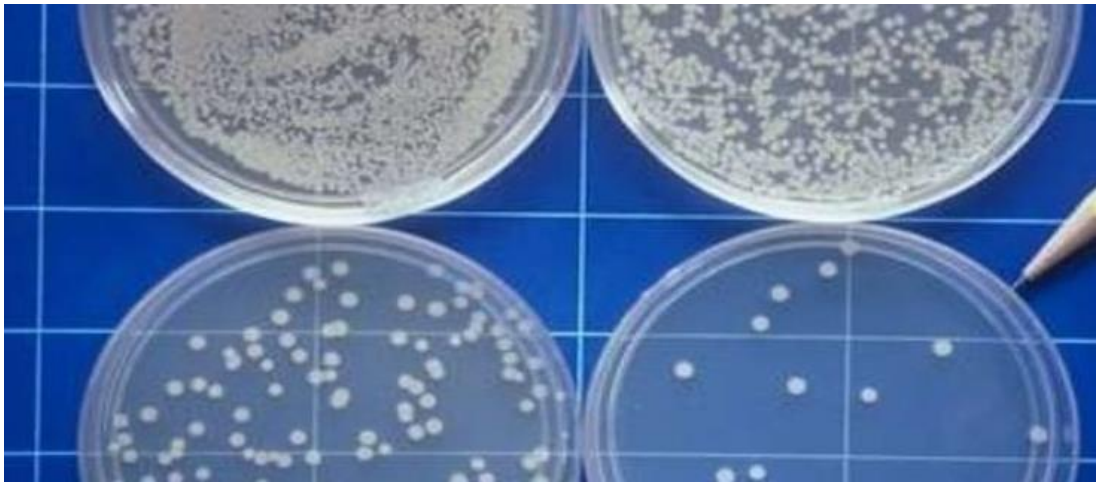
If studies are required- Infectivity/pathogenicity?

- Include consideration of infectivity /pathogenicity (for non-target organisms groups) unless not applicable? Waiver possible?
- Study duration sufficient?
- US EPA guidelines



Risk to birds and mammals: is Infectivity/pathogenicity needed?

- For example consideration of survival of micro-organism at body temperature: *The micro-organism is unable to grow at temperatures above 35 °C*
- Requires supporting information e.g. studies looking at the impact of temperature on survival



Birds and mammals: If Toxicity studies required

- Previous slides and argumentation may mean studies are not required
- Commissioning vertebrate studies requires justification under 1107/2009
- Recommend contacting regulator- birds and mammals
- How to consider in risk assessment section…

Risk assessment for birds and mammals

- EFSA bird and mammal guidance 2009?
- TER approach

$$TER = \frac{LD_{50}}{DDD}$$

Risk to birds and mammals

- May be used as illustrative but is not validated for micro-organisms…
- Weight of evidence approach required

Metabolites of concern

- Consideration of metabolites required
- Draft guidance going through commenting
- Key area that is sometimes missed
- Metabolites identified? Consider fate- produced in situ, is exposure lower or comparable to natural levels? Can exposure to non-target organisms be excluded?

Product data required?

- Consideration of co-formulants in part C, are formulation studies required or can toxicity be predicted based on active?

Botanicals

- Plant extracts may not be non-toxic and mitigation could be required.
- Consider exposure (fate) including ‘context’ likely to be lower or comparable to natural levels?
- Testing strategy should be in-line with proposed use and relevant exposure situations
- Use literature data
- Consider components of concern

Final thoughts on dossier completion

- ‘Case by case’ and waivers possible but need justification and supporting information
- Consistent argumentation throughout dossiers e.g. efficacy and ecotoxicology
- Testing strategy- are studies required? avoid additional vertebrate testing, test species appropriate to GAP, consider other factors: weight of evidence- identity, background levels etc before testing.
- Literature data (following EFSA guidance)

References

- SANCO/12117/2012: Working document to the Environmental Safety Evaluation of Microbial Biocontrols Agents
- SANCO/11470/2012: Guidance document on botanical active substances used in plant protection products
- EFSA 2014;12(3):3615: EFSA Guidance Document (protected crops)
- EFSA 2011;9(2):2092: EFSA literature review guidance
- OECD monograph guidance- Pheromones and semiochemicals- September 2002
- Draft guidance document metabolites of concern- sent for public consultation (link to pdf document below): https://www.efsa.europa.eu/en/consultations/call/190417-0

HSE (UK) colleagues present:

- Tom Fisher- Ecotoxicologist
- Valerie Swaine- Toxicologist
- John Dale- Pesticide Active Substances and Operational Policy team (PASOP)
- Lisa Moakes- PASOP and biopesticides champion for UK
- HSE enquiry email: CRD.Information.Management@hse.gov.uk
- http://www.hse.gov.uk/pesticides/