BCPC Workshop
Biopesticides

John Dale, Lisa Moakes

What are we Going to Cover?

The workshop is in two parts:

- Biopesticide Data Requirements
- Microbial Trials Permit Approaches

- We will be looking for you to provide your thoughts on several questions we have posed on these topics

Part 1: Data Requirements Dilemma

Data Requirements Background

- Retained Regulation (EC) 1107/2009
  - Lays down the rules and procedures for approval of active substances and authorisation of products
- The only data requirements we have are:
  - Regulation (EU) 283/2013 - setting data requirements for active substances
  - Regulation (EU) 284/2013 - setting data requirements for PPP's
  - Microbial data requirements are listed separately in Part B

Biopesticide Data Requirements

Therefore,

Plant Extracts/Botanicals, Semiochemicals/Pheromones are covered by the Part A ‘chemical data requirements’, supplemented by guidance documents

Microbials covered by the specific Part B ‘microbial requirements, but also supported by a range of guidance




Requirements can be addressed by studies, public domain data and/or scientifically supported arguments

GB Data Requirements

This is the same position as in the EU. However, in the EU revised microbial data requirements were published last year, so we now have divergence

The revision followed increased dossier experience and recognition that some of the original requirements were not always clear or suitable

Similar issues have been discussed amongst international regulators and improvements are still ongoing with further guidance continually being developed

The Data Requirement Dilemmas

With this background in mind we would like you to think about the following questions:

1) How would you regulate Biopesticides if you were starting with a blank page?

2 a) Do plant extracts and semiochemicals need their own specific data requirements or is the current system (using Part A, plus guidance) acceptable, providing flexibility to cover the wide range of active types and new technologies?

2 b) If they had their own requirements, what would they look like?

The Data Requirement Dilemmas (2)

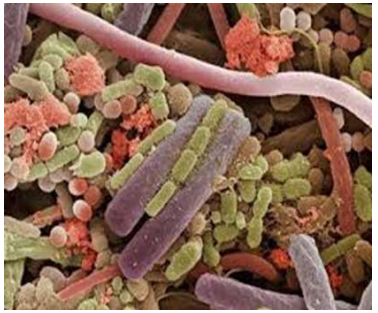
3. Are the new EU Microbial requirements an improvement to the old requirements? If not, what would you remove/add/improve?
4. From a dossier preparation point of view is it better/more cost attractive to have more aligned requirements with the EU than GB using the current requirements or developing GB specific requirements?
5. How could dossiers from other parts of the globe be used and presented to address GB requirements?
6. Would an option be to use the OECD format and data requirement numbering system to submit data to GB?
7. IUCLID – should GB consider adopting this as the dossier submission format? What are the pros and cons?

Part 2: Microbial Trials Permits

Microbial Trials Permits Background

Retained regulation (EC) 1107/2009 Article 54 Research & Development

- Administrative Trials Permit
- Extrapolated Trials Permit
- Consumer-assessed Trials Permit
- Fully assessed Trials Permit



Regulatory regime needs to

- Avoid harm to human health and unacceptable effects on the environment;
- Facilitate and not impede the adoption of technological developments that have the potential to improve sustainability

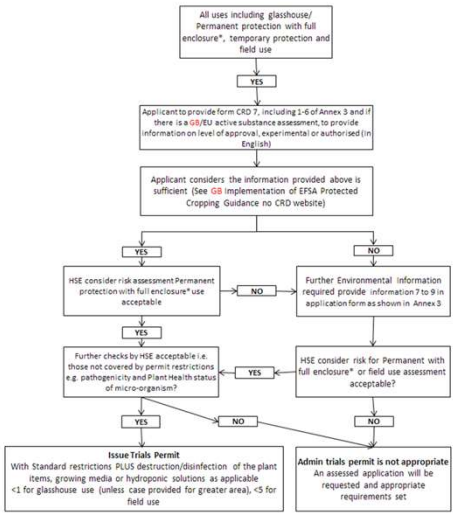
Microbial Admin Trials Permits (MATP)

- Types of Biopesticide Administrative Trials Permit
  - Botanicals, pheromones (standard ATPs) – risk mitigated by permit restricted area 5 ha and restrictions which safeguard human health and environment
  - Microbials (MATPs) – require additional consideration due to potential for proliferation
- CRD is at a crucial stage in considering the process for MATPs. Therefore, we value your input to develop most appropriate system

Currently

Following previous external consultation HSE is:

- Considering the minimum level of information required to provide reassurance on any consequences from microbial release
- Considering what information is suitable to request based on data requirements
- Considering a tiered approach based on known risk
- Drafting more detailed assistance on our website for when considering microbial trials applications
- Considering divergence with conventional permits



MATP Challenges

At the early-stage of trials permit requests an applicant's knowledge of their organisms varies

Key challenges for the applicant and in turn HSE are:

- Identity
- Species v/s strain level information, often limited/non-existent
- Indigenous vs Non-indigenous
- Environment of origin – a microbials natural environment vs PPP use
- Weight of evidence – relevance of public domain information

Workshop: Scenarios

Should we differentiate risks between microbials and on what basis?

A. Applicant submits MATP for a new baculovirus widely known to be relatively homogeneous species well studied in public domain information, pest specific, and the new isolate originates from Brazil

B. Applicant submits MATP for soil dwelling bacteria species isolated in UK, which is part of the *Bacillus subtilis species complex documented* in public domain information for many decades, but no specific strain information

C. Applicant submits MATP bacterial Isolate from Alaskan Permafrost relatively unknown species

For each Scenario, please consider

In your groups:

1) What level of data/information do you consider appropriate and proportionate for a MATP and is it the same for each scenario, OR do the potential adverse consequences of some scenarios justify more?

Please also consider:

2) What would your priorities be (e.g. cost, speed of issue of permit)?
3) Currently if a MATP is refused an assessed permit is required before a trials permit can be issued, with a target of 1 year and cost depending on the amount of data/information required. Would this prevent you from moving forward with approval in UK?
4) Would you support a separate approach to microbials permits from chemicals?
5) Any other comments on Admin trials permits for conventional/Botanical/Pheromone

Let us have your thoughts.