

# Challenges of the bee risk assessment in product (re)authorisation

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**Content of Presentation** 



### Brief overview of Current Bee data Requirements & Guidance

New data and approaches that industry can bring to meet the new guidance challenges?

Dealing with the implications on PPP (re)authorisation process





# **Overview of Current Bee data Requirements & Guidance**



### **Current Regulatory Requirements & Guidance for bees**

### **Implemented Guidance**

- EPPO Risk Assessment Scheme for Honeybees
- SANCO Terrestrial Ecotox Guidance Document
- EC Plant Protection Product Directive 1107/ 2009
  - Data Requirements (EC Regulation No. 283 and 284/2013)
  - Uniform Principles (EC Regulation 546/2011)

#### Guidance not yet adopted but likely to be pushed through



GUIDANCE OF EFSA

**EFSA** Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)<sup>1</sup>

European Food Safety Authority<sup>2,3</sup>

PRAPeR 133: Recurring Issues in Ecotox:

- Implement Tier 1 & General Principles of Higher-tier for Honey Bee:
- Did not have full support of all MSs involved.









### **EFSA Bee Guidance Overview of Challenges**

- Guidance complex and overly-conservative
  - Multiple new exposure & risk assessment calculations
  - 1<sup>st</sup> tier not an effective screening tool to differentiate potential risk
  - Not consistent with Uniform Principles and goes beyond 1107 data requirements

### Guidance is Impractical

- No agreed guidelines for many of the new studies & endpoints
- Field Study Replication & Separation Requirements
  Impossible to meet!

### Regulatory Product impact

- ECPA Impact assessment predict that
  - Insecticides are unregisterable
  - Most fungicides and herbicides will also fail risk assessment

ECPA impact analysis confirmed by recent EFSAAS herbicide and fungicide evaluations









# New data and approaches industry can bring to meet the new guidance challenges?



### Possible risk refinements with new data



### Potential exposure refinements

- Pollen & nectar residue estimates ECPA supporting EFSA initiative
- Sugar content of nectar
- Relevance of guttation residues to Risk Assessment
- Honeybee foraging estimates ie using New RFID studies
- In-field Flowering weeds scenario using data from herbicide efficacy trials



% of weed recordings which were above a flowering growth stage

However, these refinement alone will not alter high product failure rate

Data from: Maynard et at 2015. Weeds in the treated field - a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium), September 15-17, 2014



### **Development of New Study Methodologies**



### Laboratory Studies with Bumble bees and Solitary bees

- Bumble bees : OECD acute oral/contact in next 2 years
- Solitary bees: Acute contact theoretically feasible but acute oral a big challenge.
- Chronic & larval studies ????

### Semi-field/field tests





- Honeybees: continue to comply with the 284/2013 data requirements using EPPO Field Testing Guideline <u>but</u>:
- <u>Improve</u> EPPO design to <u>move towards</u> the requirements

of EFSA Guidance

Cannot meet the EFSA statistical

significance target of 7%.



 Bumble bees & Solitary bees: No standardized higher tier testing methods are available, yet; just research type testing approaches



### ECPA Fully support the Protection Goal Principle of "negligible effect on colonies"

### However do not support the proposed measure of "Negligible Effect" ie: "7% effect on Colony Strength"

 New BEEHAVE modelling indicates reductions in colony size up to 20 -30% have no long-term term impacts at the colony level on development/survival.









# Dealing with the implications on PPP (re)-authorisation process



### Case Study: AIR 3 – Ethofumesate (EFSA Journal 2016, 14(1): 4374): Not yet Discussed at SCoPAFF

### Herbicide recently evaluated

- Use on Sugarbeet, fodder beet and red beet
- Low inherent toxicity to honeybees
- Crops will be <u>harvested before flowering</u>

### EFSA Conclusion on Bees

- Used EFSA guidance document on bees
- low acute and chronic risk to bees but:
- Data gaps & outstanding risk were identified
  - in-field weeds, field margin, adjacent and succeeding crops, metabolites in pollen/nectar,
  - No data to evaluate risks to bumble bees & Solitary bees

Need an agreed approach for product re-authorisation!!





### <u>Challenges</u> for RMS, Zonal and MS Product Authorisations



- RMS approach (eg waivers) not accepted by EFSA in AIR-2 & 3 eg Fenamidone (AIR-2: EFSA 2016, 4406) & Isoxaflutole (AIR-3: EFSA 2016, 4416)
- Active Substance approval may highlight need for further review at PPP Authorisation
  - How will MS/Zones deal with
    - Technical Capability to follow the complexity?
    - High risks identified for low toxicity Products?
    - Harmonisation between MSs?

### Additional PPP MS Authorisation Challenges

- Extensions of use to new crops
- Field studies don't meet EFSA Guidance
- Cannot meet Protection Goals
- Practical risk mitigation options (e.g. pre-flowering restrictions) cannot cover all exposure routes that now need to be considered. E.g. field margins, flowering weeds, guttation puddles etc.



### <u>Way Forward</u> with Zonal and Member State PPP Authorisations



→ ECPA want to work together to meet these Challenges



- Continue to develop exposure refinement data and approaches
- Continue to develop new methodologies for new requirements
- Improve current honeybee Field/Semi Field testing approaches
- Improve Honeybee Modelling approaches to investigate <u>measure</u> of "Negligible Effects" eg BEEHAVE Pesticide Module

What opportunities are there for a Technical dialogue to agree & harmonize refinement options?

### **Overall Conclusions**



- The EFSA bee guidance document (not noted)
  - Goes well beyond Uniform Principles and 1107
  - Is highly conservative and complex
  - Doesn't meet best available science anymore
- PRAPeR 133 used to implement un-adopted EFSA Bee Guidance
- Commission committed to unblock it ASAP
- Potential new ECPA data and refinements to offer
  - Various exposure refinements with data
  - Developing new study methodologies

# But these refinement will not significantly alter the high failure rate of products and unregisterability of insecticides.

 Therefore, need to revisit the "<u>Measure</u>" (7%) of "Negligible Effect" Protection Goal and need time to develop new test guidelines.

### **Overall Conclusions**



### Implications for RMSs, MSs for the PPP (re)-authorisation process

- Leaves more issue to be managed at MS level
  - Frequent incomplete risk assessments moved to MSs
  - Can Member States approve Products with bee data requirements?
  - Label extensions of use?
  - Increased complexity and expert resource requirements at MS

### $\rightarrow$ Way forward

- ECPA looking for opportunities to develop technical solutions to meet these Challenges
- Technical Workshop between MSs and ECPA to fulfil new data requirements?
- Aim to harmonise the post active substance approval <u>Product registration</u> <u>approach</u> and refinement options for EFSA Bee Guidance

### Legal Challenges for AS Approvals



- Implementation of EFSA BG will result in virtually all EFSA Active Substance Peer Review Conclusions having Data Gaps for Bees
  - <u>COM have option to approve AS with Confirmatory Data request</u>
- Recent Ombudsman Ruling more restrictive use of confirmatory data??

Very few/No AS approvals (ie with no data gaps??)



AS approvals with data gaps & legal challenge?? <u>eg Sulfoxaflor</u>

More needs to be done to reduce uncertainty for Notifiers but also for Commission and MSs!!



### **Thank You for your attention**

