SUMITOMO CHEMICAL
AgroSolutions Division - International

VALENT BIOSCIENCES

Ongoing review of the EFSA guidance on risk assessment of pesticides and bees: IBMA contributions

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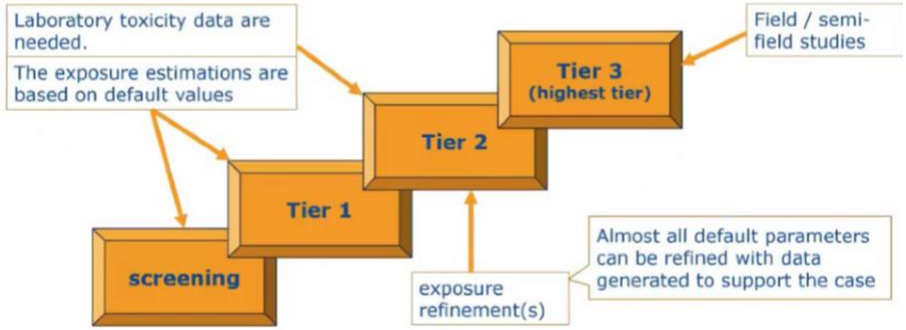
IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

2013 EFSA Bee Guidance

- In 2013, EFSA adopted the Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
- 3 groups of bee species: honey bees, bumble bees, solitary bees
- 3 application methods: spray, seed treatment, granules
- 3 exposure routes: contact, dietary, water
- 3 (+1) risk cases: acute, chronic, larvae
- 5 scenarios: treated crop, in-field weeds, field margins, adjacent crop, next crop
- 3 (+1) tiers



Background

- However, 2013 EFSA guidance has not been fully implemented due to the lack of consensus between Member States
- In March 2019 EFSA was mandated by European Commission to review the guidance because:
  - A majority of Member States requesting updates
  - New scientific evidence has become available since 2013
- EFSA committed to:
  - Finalise the work (pending definitions of Protection Goals by the Risk Managers) in March 2021
  - **Involve stakeholders and MSs** throughout the process

EFSA Stakeholder Consultation Group

5. List of selected stakeholders

Name of Organisation	Stakeholder Category	Name of Expert
European Crop Protection Association (ECPA)	Business and food industry	Mark Miles
European Seed Association (ESA)	Business and food industry	Anne Alix
International Biocontrol Manufacturers Association (IBMA)	Business and food industry	Silvia Hinarejos
Pesticide Action Network (PAN) Europe	Environmental/health NGOs and advocacy groups	Martin Dermine
Pollinis*	Environmental/health NGOs and advocacy groups	Barbara Berardi Tadié
Beelife European Beekeeping Coordination	Environmental/health NGOs and advocacy groups	Noa Simon Delso
APIMONDIA*	Farmers and primary producers	Fani Hatjina
Copa and Cogeca	Farmers and primary producers	Chris Hartfield
International Confederation of European Beet Growers (C.I.B.E.)	Farmers and primary producers	Alexander Krick

* *Association is invited to register as EFSA stakeholder organisation.*

- EFSA call for nominations of stakeholder bee experts in May 2019
- 17 applications received
- Based on the predefined criteria, **9 selected**
- All the **9 organisations plus MSs** are involved in EFSA ad-hoc consultations

IBMA ad hoc expert group

Expert Members	
Apis	Ben Jones *(until March 2020)*
Biotecnologie BT	Monica Colli
CBC (Europe)	Edith Ladurner
IBMA	Ulf Heilig , Jennifer Lewis
IPM Impact	Guido Sterk
Koppert	Willem Ravensberg
Sumitomo Chemical	**Silvia Hinarejos - IBMA's expert in the EFSA SHs**
Suterra	Alessandra Moccia

Progress of the review of the bee GD: overview

March 2019

- WG setting
- ad hoc SH group setting

June 2019

Sep 2019

1st Consultation of SHs and MSs on the (EFSA, 2013)

Oct 2019

2nd Consultation of SHs and MSs on the protocol for the background mortality

Feb 2020

1st Consultation of Risk Managers on SPGs :

- SPGs and trigger values in the EFSA (2013)
- Discussion and feedback

- Outline on procedural aspects/timelines
- Collaborating with ECHA
- Project on background mortality
- Development of the protocol for ToR3 and ToR4

April 2020

Apr 2020

3rd Consultation/workshop with SHs and MSs on the protocol for ToR3 and 4

Implementation of the protocol for ToR3 and ToR4:

- Perform the EKE for the attractiveness to pollen and nectar
- Systematic literature review for food consumption
- Systematic literature review for the sugar content in nectar
- Update of the residue database
- Relevance of exposure scenarios (weeds, water)
- etc

Jun 2020

2nd Consultation of Risk Managers on SPGs:

- Development of the supportive document for RMs
- Implementation of the approach selected by RMs

October 2020

3rd Consultation of Risk Managers on SPGs

Finalisation of the GD (once SPG are defined):

- Revision of the trigger values
- Revision of the higher tier requirements

SHs: Stakeholder Consultation Group

Aspects of the Bee GD under Review (1/2)

- Review of the evidence on bee background mortality - *Report published 28 July 2020**
- Systematic literature review for food consumption (HB, BB and SB)
- Systematic literature review for the sugar content in nectar of various crops
- Expert Knowledge Elicitations (EKE) for the attractiveness to pollen &nectar - *6 experts selected*
- Systematic revision of the available residue data in pollen&nectar
- Inter-species sensitivity analysis

* http://www.efsa.europa.eu/en/supporting/pub/en-1880

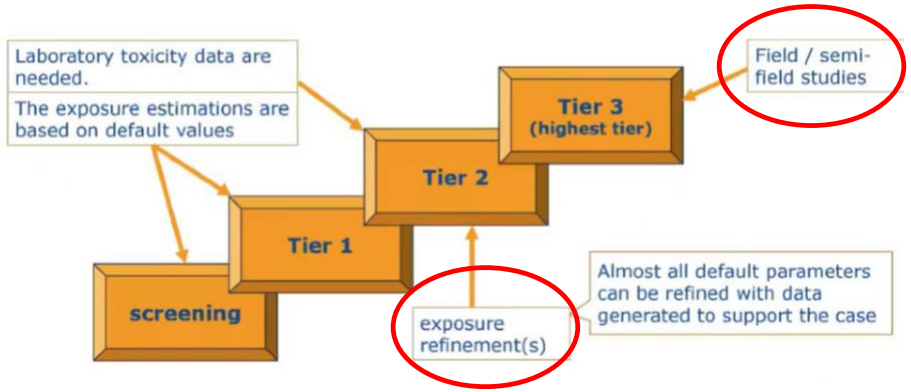
Aspects of the Bee GD under Review (2/2)

- Analysis of dose-response (extensive review) useful for:
  - Extrapolation factors
  - Endpoints definition
  - Trigger values
- Review of the relevance weed/water/succeeding crop scenarios
- Definition of default parameters included in the oral exposure model
- Mixture toxicity and risk assessment
- Risk assessment metabolites
- Consideration of sublethal effect, accumulative effect, recommendations for exposure refinement

Other aspects to be reviewed after the SPG setting

- Revision of the higher tier requirements:
  - to detect the derived threshold of acceptable effects and how to assess the exposure

- Revision of the methodology for the trigger values:
  - to calibrate the lower tier risk assessment and revise the trigger values



Endpoint	Honey bees	Bumble bees	Solitary bees
Acute contact LD50 (DW; SUW)	HQ <42 HQ <85	HQ <7 HQ <14	HQ <8 HQ <16
Acute oral LD50	ETR <0.2	ETR <0.036	ETR <0.04
Chronic oral LC50	ETR <0.03	ETR <0.0048	ETR <0.0054
Larval toxicity NOEC	ETR <0.2	ETR <0.2	ETR <0.2
Development hypopharyngeal glands	ETR <1	-	-

IBMA: contributions relating to biologicals&semiochemicals

- Considered part of the EFSA mandate to review the current methodology once the Risk Managers (MS) have decided the SPGs:
  - In Risk Manager consultations/workshops on SPGs, 3 typical biological application types (1 generalist microbial, 1 specialist microbial and 1 semiochemical dispenser) were concluded to have minimal negative impact on ecosystem services.
  - Therefore, it would be valuable that EFSA includes scenarios specific for microbial PPPs and semiochemicals which relate to the reduced impact already established by Risk Managers.

IBMA: contributions relating to biologicals&semiochemicals

- Effect Assessment:
  - EFSA refers to OECD guidelines, validated and suitable for chemical pesticides only
  - Current practice for microbials is to use OCSPP (US) guidelines to assess pathogenicity/infectivity
  - The differences between the OECD and OCSPP guidelines can lead to several issues rendering the proposed bee risk assessment inappropriate
  - We informed that the International Commission on Plant Pollinator Relations (ICPPR)-Microbial WG is producing for OECD a white paper on state-of-art on testing methods for microbials, i.e. describing the available guidelines limitations for testing microbials.

IBMA: contributions relating to biologicals&semiochemicals

- Exposure Assessment:
  - Current risk assessment practice for biologicals is more qualitative than quantitative (as proposed by EFSA). Will be challenging to try to estimate exposure given their specificities
  - If data are available, waivers should be still used if negligible or minimal exposure.
- Non-Apis bees:
  - IBMA has members producing managed bumble bees and solitary bees for commercial pollination. Knowledge and insights has been provided.


IBMA: contributions relating to biologicals&semiochemicals

- Overall, after 3 consultations, our conclusion is that biologicals and their specificities are not properly considered in the future EFSA guidance. Are there excluded?

[question in the April 2020 workshop]

- According to EFSA feedback*, the scope of the current review is for* ***chemical*** *pesticides*

Conclusive remarks & Next steps

- Regarding the overall EFSA progress:
  - Due to the complexity of the project and the uncertainties caused by COVID-19, the current deadline of March 2021 may change
  - The scientific process for defining the SPGs for bees is driven by the ongoing parallel Risk Managers (MSs) discussions on ***what to protect*** and ***to which extent***, and the EFSA review depends on those decisions to progress
  - To support the decision-making process by Risk Managers, EFSA identified 4 methodological approaches (workshop organised by DG SANTE on 30 June).
    - Making use of population models was the option preferred by MS
    - A second preliminary report on how this approach is implemented by EFSA will be issued to Risk Managers for their 3rd consultation on SPGs (report will be published on the EFSA website, **SHs will be pre-notified**)

Conclusive remarks & Next steps

- Regarding the impact on IBMA:
  - IBMA will keep reminding EFSA, to explicitly exclude biologicals, at least microbials, in the final revised guidance.
  - Unclear at this stage the impact on pheromones or botanicals, currently the EFSA guidance is applied for those. We will need further clarity by EFSA (and also in other the discussions between IBMA and DG SANTE on data requirements).
  - We don’t expect new consultations of the SHs but should have the opportunity to comment on the draft new guidance before it is finalised.

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