ZUUR A.F., E.N. IENO, C.S. ELPHICK, 2010: A protocol for data exploration to avoid common statistical problems Methods in Ecology and Evolution 1:3-14.

ZUUR A.F., E.N. IENO, R. FRECKLETON, 2016: A protocol for conducting and presenting results of regression-type analyses Methods in Ecology and Evolution 7:636-645.

1.15 ICPPR WG Semi-field and field Report and Discussion

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DOI 10.5073/jka.2020.465.015

Abstract

The ICPPR Semi-Field/Field Testing (SF/FT) workgroup consists of several 'writing groups' that are focused developing technical guidance that is focused on 4 separate but related topics: 1) designing and conducting pollen and nectar residue studies, 2) conducting large scale colony feeding studies, 3) updating guidance for conducting semi-field tunnel studies, and 4) design and interpretation of full field studies with bees. What follows is the current status of each of these activities.

Bee-Relevant Field Residue Studies. At the present time, detailed regulatory guidance for conducting field studies of pesticide residues in with pollen and nectar is lacking. Therefore, the Residue Study Writing Group is drafting guidance that is designed to increase the consistency, defensibility and utility of bee-relevant residue studies for use in regulatory risk assessment. Importantly, this guidance is being tailored to address specific regulatory objectives of bee-relevant residue studies which may vary among pesticides and regulatory authorities. Areas of focus include guidance on:

Spatial Scale: (*e.g.,* defining representative sites, minimum # of sites to include)
Temporal Scale: (*e.g.,* sample timing, intervals, number of samples, # replicates)
Crop Selection & Sampling Methods: (*e.g.,* selecting appropriate crops and matrices for sampling, choosing sampling methods)
Pesticide Application: (*e.g.,* determining the appropriate application timing, rate, intervals)
Analytical methods: (*e.g.,* methods validation/recovery, LOQ/LOD)
Statistical analysis: (determination of DT50s, consideration of outliers)

To date, existing regulatory guidance relating to bee-relevant residue studies has been compiled and summarized, in addition to common regulatory objectives of such studies. Based on these objectives, technical guidance on the aforementioned topics is being drafted. In addition, bee-relevant residue data are from EPA and EFSA sources being compiled into a common database for additional analysis. Draft guidance for review by the SF/FT is expected during the summer of 2020 with a final guidance being drafted by the end of 2020.

Current Residue Writing Group Members: Keith Sappington (chair), Jeremey Barnekow, Sigrun Bocksch, Silvia Hinarejos, Stefan Kimmel, Silvio Knäbe, Raj Singh

Large-Scale Colony Feeding Studies. Within the last decade, regulatory authorities in Europe, North America, and elsewhere have greatly expanded their procedures for quantifying pesticide risks to bees to include a tiered approach. As a higher tier level approach, regulatory authorities in North America have quantitatively used results from "Large Scale Colony Feeding Studies" (LSCFS) to associate honey bee colony-level impacts with exposure to pesticides mostly via in-hive sucrose solution in a concentration-dependent manner. Examples of LSCFS with exposure to pesticides via pollen patties are more limited. Because of its design, the LSCFS is not specific to any particular crop and can be directly compared to nectar and pollen residues from multiple crops. The LSCFS design involves a relatively large number of replicates (*e.g.*, 12 separate replicate/apiaries), multiple (*e.g.*, five) treatment levels, and periodic colony condition assessments (*e.g.,* 8-9 assessments over 12+ months, including pre-exposure, exposure and post-exposure periods). Despite its continued use in regulatory risk assessments, no formal regulatory protocol exists for conducting the LSCFS.

Therefore, the LSCFS Writing Group is drafting guidance to increase the consistency, defensibility and utility of LSCFS for use in regulatory risk assessment. This guidance is intended to be flexible enough to be used by various stakeholders including regulators, academic and industry researchers, to address specific risk assessment scenarios. Areas of focus include guidance on:

Regulatory Objectives
Hive management – use of standard local beekeeping practices
Study design, site locations and hive placement
Overwintering and supplemental feeding
Varroa and *Nosema* treatment
Swarm control
Use of queen excluders
Colony size and condition (initial size, growth and overwintering considerations)
Genetics
Start date of study and length of exposure
Sampling scheme for exposure characterization
Residue analysis for metabolites
Exposure to pesticides from other food sources (other than artificial feeding)
Robbing and control contamination
Observer bias
Endpoints (including estimates of adults, eggs, larvae, pupae, and food stores, overwinter survival, *Varroa*, *Nosema*, hive weight)
Experimental design, statistical analysis and statistical power
Further research needs

To date, the majority of the components of the guidance have been discussed within the writing group and incorporated into a draft technical guidance. The statistical analysis component of the guidance is still under development. Draft guidance for review by the SF/FT is expected during the summer of 2020 with a final guidance document being published by the end of 2020.

Current LSCFS Writing Group Members: Barbara Martinovic Barrett (co-chair), Allen Olmstead (co-chair), Sigrun Bocksch, Max Feken, Connie Hart, Silvia Hinarejos, Keith Sappington

Semi-Field Tunnel Studies. In order to reflect the recent development in semi field testing, the semi-field writing group is revising the tunnel study portion of the EPPO 170 document. The aim is to provide more standardized procedure for semi-field testing in order to test the impact of a product on honey bee survival, colony development and behaviour under more realistic conditions compared to laboratory studies/conditions. There is a large overlap of semi field studies with OECD 75 studies, field studies and residue studies. The semi field working group is starting to update the existing guidance EPPO 170 for semi field (and field tests) with the focus on the semi field requirements. Areas of focus include flexibility of use by various countries and guidance on:

Tunnel design
Size of tunnels
Size of colonies
Homogeneity of colonies
Study conduct

Current Semi-Field Study Writing Group Members: Heike Gaetschenberger (co-chair), Gundula Gonsior (co-chair), Barbara Martinovic Barrett, Hervé Giffard, Wayne Hou, Reed Johnson, Stefan Kimmel, Markus Persigehl, Josep Roig, Sabine Hecht-Rost, Ulrich Zumkier

Full Field Studies. Full field studies are intended to address specific uncertainties (*i.e.*, risk hypotheses) which have been identified through lower-tier studies and/or through the open literature under reasonable worst-case exposure scenarios in the field. The ICPPR Full Field Study Writing Group has been developing a common approach to conducting field studies with honeybees. Initially, the regulatory objectives and protection have been outlined. The protection

goals include contribution to bee biodiversity, provision of pollination services and production of hive products. The protection goals in turn dictate assessment endpoints for which specific measurement endpoints are identified. For field studies, measurement endpoints depend on the risk hypothesis tested and the nature of uncertainties identified in lower-tier tests. The primary measurement endpoints for field studies include colony strength, brood pattern and development, foraging activity, food storage and consumption, worker mortality and behaviour and queen and colony health. A draft guideline covering these primary measurement endpoints has been written and is available for comment. A key aspect of the guidance is the degree of replication possible versus the practical limitations of conducting large scale field studies. An exercise will be undertaken in 2020 to determine the statistical power of existing field studies to detect certain levels of effects related to the primary measurement endpoints. This will inform the writing group of the optimal replication required to detect effects whilst maintain a methodology that is practically possible to follow in the field.