Field trials on trial - Evaluation of the information of honey bee field test for pesticide risk assessment

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Field trials (FT) have been traditionally employed as tests used to ultimately determine the risk of a pesticide for honey bees in the risk assessment scheme, the so called highest tier. Methodological guidelines exist for their development (e.g. EPPO 170, CEB 230); however, either they are not systematically used when developing tests for regulatory purposes or they remain imprecise. As a result, risk assessors have access to variable information for the authorisation of pesticides in Europe. The objective of this study is to evaluate the quality of FTs performed to date for regulatory purposes.

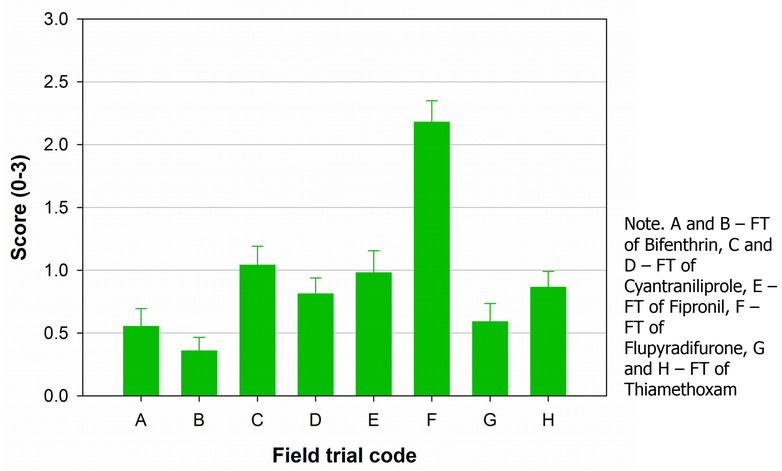
Field trial on sunflower with honey bee colonies

Material and Methods

Test summaries publicly available in the Draft Assessment Reports (DARs) of different active ingredients (aa.ii., n=5) were randomly allocated and evaluated by bee ecotoxicologists (n=18), each one receiving 2 summaries. Reviewers did not know either the a.i. nor the authors/company/etc developing the study allocated to them. Codes were provided for aa.ii. with correspondence: A and B – FT of Bifenthrin, C and D – FT of Cyantraniliprole, E – FT of Fipronil, F – FT of Flupyradifurone, G and H – FT of Thiamethoxam.

The purpose of the exercise was to verify and score the quality of the information included in these summaries according to the criteria proposed by the EFSA guidance document for the risk assessment of pesticides on bees (2013)[1] related to exposure (EXi) and toxicology assessment (EFi), statistical requirements and design of the FT (DSi) and duration and frequency of assessments (FQi). Score value were: 0 - Not available. If information was available: 1 insufficient, 2 intermediate, 3 sufficient information. The questionnaire proposed can be found here: https://goo.gl/forms/7me4jFyCeZJZzttC2

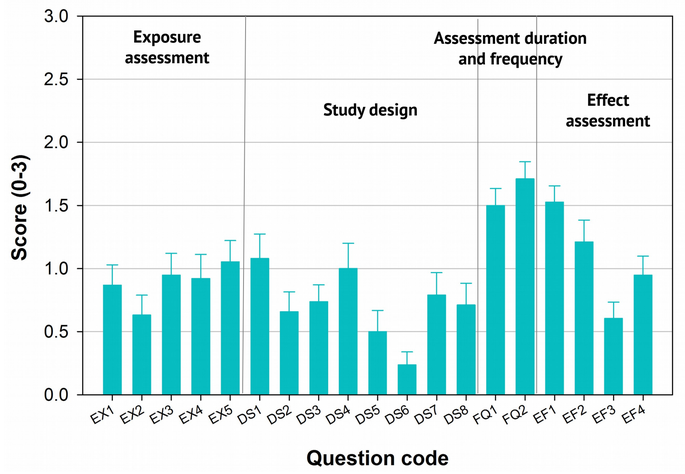
Results



Note. A and B – FT of Bifenthrin, C and D – FT of Cyantraniliprole, E – FT of Fipronil, F – FT of Flupyradifurone, G and H – FT of Thiamethoxam

Scores by field trial

Score (mean and SE) obtained by the different field studies. The highest and the lowest score was obtained by F and B, respectively. The other studies showed similar "quality". In average, all studies obtained a score lower or around 1, this means that most of the information presented in the reports were missing or insufficient. Only one study (F) showed an intermediate level of information.



Scores by assessment question

Score (mean and SE) obtained by the different questions. The questions DS6, DS5, EF3, EX2, DS2 reported the lowest score values (Score < 0.66) while the highest values were assigned to the questions FQ2, EF1, FQ1, EF2, DS1 (score > 1.07). This involve mainly poor/missing information available on the representativity and exposure of the test, while effect assessment is to a certain point better described.

Discussion and conclusion

The study showed a generalised low score of the different FT included in DARs of these authorised pesticides, indicating either missing or insufficient information available for risk assessment. Only the study with highest score, F, had an average score over 2, indicating intermediate level of information provided. One plausible reason behind this finding is the evolution in methodology and awareness on bee toxicology in the recent years. F was carried out in 2010, while the majority of the others were from 1981-2000. However, provided that FT C/D are from 2011, the reason may be linked to the risk assessor in charge of the dossier or the company owing the a.i.

The score reported for the single questions shows that a large improvement is necessary in the study design, in particular, a shortcoming has been highlighted in the level of representation of the sites for which the authorisation is requested, the description of the exposure level and the lack of information of overwintering success.

Assuming the information necessary for risk assessment was available but not transferred by the risk assessor into the summary, the missing information is problematic from a transparency point of view. Otherwise, assuming the information was not provided in the FT report, the missing information is worrying, considering the decisive role of FT for decision making: negligible-high risk to bees. We recommend (1) harmonised reporting by for example proposing a template of the summary studies to be included in the DAR; (2) prompt implementation of the FT methodological recommendations included in the EFSA Guidance Document; and (3) include residue analyses in different bee matrices (e.g. pollen, nectar, honey, plant etc.) to determine exposure.

Reference [1] EFSA. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal. 2013;11: 3295 [266 pp.]. doi:10.2903/j.efsa.2013.3295

Acknowledgements We thank COLOSS for the support to the Task Force without which the development of this work would have been more difficult.