

1.20 OECD GD 239 Honey bee larvae in vitro testing and solvents: on the job training

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Abstract

With adopting the OECD guidance document 239 for in vitro bee larvae repeated exposure testing in the laboratory, a new guidance became final without taking into account several pending issues and unsolved problems still to take care of. Important aspects to be taken into account is the use of solvents when testing practically insoluble compounds (e.g., during active substance testing), as well as confirmed homogeneity of substance within the final feeding solutions.

Testing of the active ingredient as technical instead of the corresponding formulation for registration purposes is requested from, but not only limited to US and Canadian authorities, several other authorities around the globe seem to follow that approach. Having in mind the high sensitivity and susceptibility of the young larvae reared in the test, this leads to quite some problems in the practicability of the test itself.

The here presented results and methodology shall share experience and lessons learned from the past years for this specific test, further on a technical approach to make the use of solvents helpful but not harmful. Further on, adaptations and modifications on the analytical verifications required for this study are shown and being put on discussion. Overall a feasible way of adaption and modification for this highly discussed and still criticized test system is presented, the improvements shall be seen as turning this setup into a more reliable and reproducible study design helpful for assessing potential risks during the process of registration of plant protection products and chemicals.

1.21 Improving pesticide regulation by use of impact analyses: A case study for bees

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Abstract

When changes to regulatory guidance for risk assessment are proposed it is necessary to undertake an impact analysis to assess whether they bring the desired improvement to a risk assessment and reliability of the outcomes to inform decision making. In particular impact analyses should estimate the chances of getting both false negative (concluding low risk where more research is needed) and false positive outcomes (concluding high risks where the product is of low risk). Such analyses are also used to inform on future product development costs and workload for regulatory authorities.

In this paper, we present the findings from an impact analysis conducted on the proposed EFSA bee guidance document (2013) and discuss whether the proposed guidance would provide for a cost effective and tiered approach toward the protection of bees due to the potential risks posed by the use of plant protection products. Following on from this a second impact assessment is presented based on new data generated by ECPA member companies regarding the assessment of chronic risk to bees. Critical areas are discussed and suggestions for the improvement of assess the risk assessment for plant protection products (PPP) to bees are presented.

Keywords: Honeybee, risk assessment, impact analysis, pesticide