Conservatism in first tier trigger values in pollinator risk assessment

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Background

The EFSA guidance on the risk assessment of plant protection products on bees (EFSA,2013) provides examples on the calculation of trigger values used in risk assessment. These values are based on several assumptions, i.e., the normal background mortality, the amount of mortality that a hive can withstand without negative effects (7% derived from the Khoury model) and the effect the compound has on bees. The latter is the focus of our current project. Where effect curves are standard of a sigmoid shape and are being normally analysed using non-linear regression techniques, the EFSA guidance adopts another approach and assumes a linear dose-response curve. As already stated in the guidance, this introduces a certain level of conservatism in the risk assessment because an effect level derived from a linear approach will result in a lower result than when this is derived from the true dose-response curve (**Fig 1**).

Objective

In order to test the amount of conservatism introduced by using a linear approach instead of a true dose-response curve, we analysed data from sixty-two 10d-chronic honeybee tests (oral uptake) using both methods. The data sets were kindly provided by Bayer and Syngenta.

Results

Ten of these sixty-two effect curves were omitted because they did not result in toxicity. So from this data set fifty-two effect curves were obtained comprising 18 fungicides, 13 herbicides and 21 insecticides, which were processed following the examples provided by EFSA. The $LDD_{1.43}$ (value used for the trigger calculation) was calculated using either a linear or a non-linear effect curve.

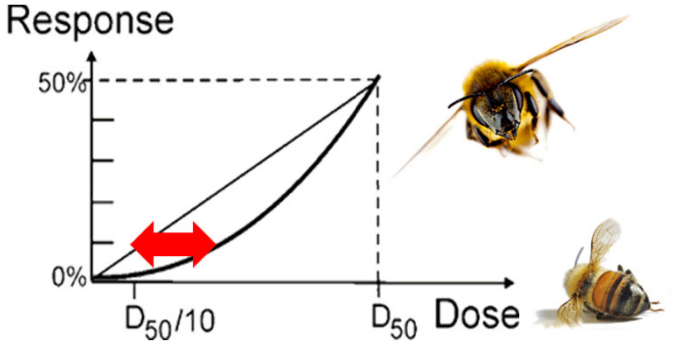

Figure 1. schematic overview of the potential difference (red) between EFSA linear approach vs true dose-effect curve.

Comparing the results of the linear and non-linear approach showed that using the linear approach gave more conservative results, up to more than a factor 30 (**Fig 2**).

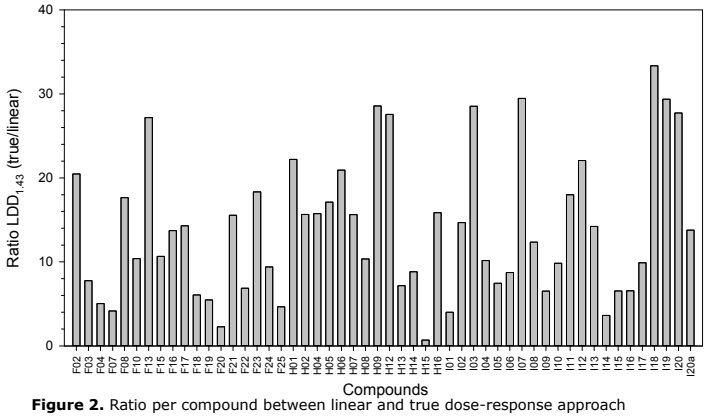

Figure 2. Ratio per compound between linear and true dose-response approach

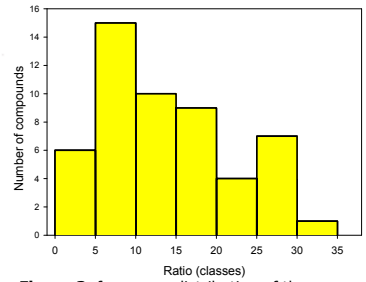

Figure 3. frequency distribution of the occurrences of ratios (grouped in classes).

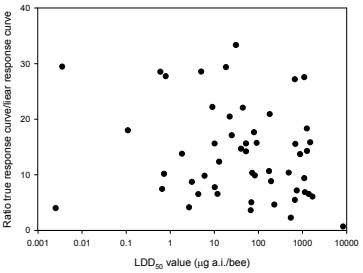

Figure 4. Relationship between the ratio and the LDD_{50} of the compound.

The majority of the calculated ratios were between 5 and 20, with one isolated ratio between 30 and 35 (**Fig 3**) indicating that the linear approach is quite conservative. This conservatism, however, was not related to toxicity as in **Fig 4** no increase or decrease in ratio was found when plotted against it's respective LDD_{50} value.

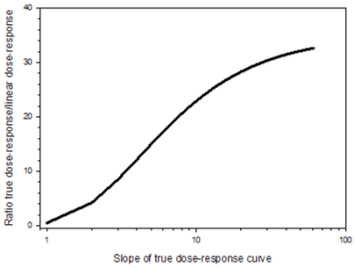

Figure 5. Relation between slope of the dose-response curve and the ratio.

Instead the slope of the curve is the main driver of the ratio (**Fig 5**). I.e. the steeper the curve, the higher the ratio and consequently the higher the introduced level of conservatism.

Conclusions

- Using a linear approach introduces more than a factor 10 conservatism in the ETR trigger value for most of the compounds
- Not toxicity of the compound but the slope of the effect curve drives the amount of conservatism introduced by assuming a linear dose-response curve

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