3. Findings

3.1 Descriptive statistics

- Fungicides and herbicides displayed similar median LDD0, values, being at least 400 times higher compared to those of insecticides. Moreover, respective NOEDDs were between 400 (fungicides) and 1200 (herbicides) times higher (Tab. 1).

- 10th percentile LDD0 and NOEDD-values derived for insecticides were about 300 times lower compared to the fungicides and 670 and 1550 times lower compared to those for herbicides, respectively.

3.2 Confirmation of impact analysis findings

- Screening RA: Low pass rates for HB for all fungicide and herbicide uses, very low rates for insecticides uses. Almost no passed uses for BB & SB using 1/10th of HB endpoints (Tab. 2) confirm the findings of the 2013 impact analysis.

- Tier 1 RA: Whereas for treated crop and weeds fungicide and herbicide uses displayed moderate pass rates for HB, those for insecticide uses were still very low. Pass rates for BB & SB in the treated crop RA were slightly higher compared to screening RA, but still very low; no BB and almost no SB passed the weed RA.

3.3 Risk assessment options to better identify potential high risk products

- Results in Table 3 are to be compared with the screening RA for HB in Table 2.

- Option 1 showed a clear discrimination between products with toxicity (insecticides) vs. non-toxic products (herbicides, most fungicides) for HB RA. Because this is based on the use of the NOEDD and a trigger of 5 the protection goal of negligible effects was met.

- Option 2 showed a similar discrimination for all types of PPPs compared to ECPO option 1 when all uses were considered, irrespectively of whether LDD0 values were available (45% of all uses) or not. Taking only those studies into consideration for which a worst-case LDD0 could have been identified pass rates for fungicides and herbicides were even higher.

- Option 3 indicated an improved level of discrimination over the EFSA screening step ensuring that the same level of protection is achieved for each product. Because it takes into account the true dose-effect relationship, more non-toxic products passed the RA, but toxic insecticides were still identified.

4. Summary and conclusions

- Risk assessments using real data confirm that the chronic risk for adults is the key driver of honey bee risk according to the EFSA Bee GD as stated in the original impact analysis [2]. In contrast the majority of fungicides and herbicides passed the Tier 1 RA for larvae [4] and even pass rates for insecticides were not even worse.

- A more selective risk assessment can be achieved by applying the standard EPP0 2010 approach based on the use of NOEDD endpoints and more realistic exposure assumptions.

- The EFSA 2013 approach can be significantly improved by taking into account the type of endpoint (NOEDD or LDD0) and the dose-response relationship in order to meet the proposed protection goal more accurately.

- Using HB endpoints for BB and SB screening and Tier 1 RA will lead to failed BB and SB chronic RA for almost all active substances and their products, as valid laboratory methods will not be available in the next future.

- Industry is committed to pursue dialog with regulatory authorities and EFSA to share our experience and data to help develop a workable way forward.[1]

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2018 Annual Meeting of SECTAE Europe, 26-30 May 2018, Helsinki, Finland.