Dutch experience with the EFSA Bee Guidance (2013)
Updated September 2017

Based upon our experience using the EFSA Bee Guidance (2013) in risk assessments for active substances, the Netherlands considers it possible to implement it, at least partially, while specific areas of the risk assessment are updated. For active substance dossiers submitted since September 2015, the MS have been using the EFSA Bee Guidance (2013) for those areas of the risk assessment for which data is available. The Netherlands has used the new Guidance for several active substances for which chronic data for honey bees and larva were available, and for which acute data for bumble bees was available. In addition, higher tier data was available in several cases. These data included residues in nectar and pollen and (semi) field studies.

The Guidance can be implemented for those areas where data is available without much problem. Higher tier data is regularly triggered for chronic risk to honey bees, even if the endpoints from the toxicity tests are quite high. This might indicate a need to adjust the trigger value for chronic risk to honey bees. If (semi) field data are available, these rarely meet the rigorous statistical standards laid down in the Guidance, however, they can be considered in a weight of evidence manner to determine whether a risk indicated in the first tier should indicate a risk from the proposed use of the product in question.

The risk from exposure to water can be performed except the risk from puddle water, for which PECrunoff is required. The Environmental Fate section currently has no agreements on how to determine this parameter, however, this could be worked upon.

The EFSA conclusions for active substances (including those assessed by the Netherlands) often indicate risks for those areas of the risk assessment where no data were available (i.e. often bumble bees, wild bees). This is because without the actual data, toxicity values of 10x are used, with an additional 10x more conservative trigger value. This may be problematic due to the extremely conservative nature of this estimation. It is typical to use a 10x toxicity value where no toxicity values are available, however, the same trigger value is then used. It is therefore highly unlikely for any substance to pass the first tier for these areas of the risk assessment assuming both 10x toxicity and a 10x lower trigger value. However, it could be decided to either not use those parts of the risk assessment until toxicity values are

available, or use the risk assessment with the same trigger values as honey bees, or using the toxicity values from honey bees directly.

In addition, EFSA often indicates concern due to missing data on accumulative toxicity or effects on the hypopharangeal gland. The Netherlands notes that the development of harmonized guidelines to test for hypopharangeal gland effects are still in a very early stage and considers that requiring such data is, therefore, not justified at the moment. However, for accumulative toxicity the required test is the same as the test for chronic toxicity. Thus, in principle, relatively accurate performance of the test could be achieved in the short-term. In the meantime, a comparison of the acute and chronic LD_{50}s also provides information on accumulative toxicity that could be used in a weight of evidence determination.

It might also be noted that the overlapping risk assessment for honey bees via EFSA (2013) and non-target arthropods may provide adequate interim information on potential risk to non-*Apis* bees, until such time as toxicity data is available and/or the new non-target arthropods Guidance is available (covering exposure routes via nectar and pollen).

In conclusion, the Netherlands considers it possible to utilize the EFSA Guidance (2013) at least partially, while specific areas of the risk assessment are updated. This provides better information on the potential chronic risk to honey bees (adult and chronic), and better information on risks via a broader number of exposure patterns. It is logical to implement the Guidance either fully, with interim instructions as to how to address those areas of the risk assessment where no data is possible, or under an implementation plan. This is preferable to the current options of the noted guidance (SANCO, 2002) with additional pieces from various areas to address the risks from other exposure routes and to other life stages, or using un-noted Guidance as per agreement between experts and EFSA, but without official requirements for notifiers/applicants.