

## **National risk assessment for the authorization of plant protection products (PPP) in Austria:**

### **Ecotoxicology Bees**

#### **Information for notifier/applicants and other interested parties**

#### **Document version 01 (June 2017)**

This document is intended to give background information on the ecotoxicological risk assessment for plant protection products, active ingredients and metabolites currently considered necessary for national authorisation of plant protection products (PPP) in Austria. The approaches for **risk assessments for bees** are shortly described hereafter. Recommendations for notifier/applicants regarding data requirements, risk assessments and risk mitigation measures are presented for especially those cases where the respective guidance document gives room for interpretation.

The ecotoxicological risk assessment for plant protection products is legally based on the Commission Regulation (EU) No 283/2013 of 1 March 2013, setting out the data requirements for active substances and (EU) No 284/2013 of 1 March 2013, setting out the data requirements for plant protection products as well as Commission Regulation (EU) No 545/2011 regarding the implementation of the data requirements and (EU) No 546/2011 of 10 June 2011 regarding uniform principles for evaluation and authorisation of plant protection products in accordance with Regulation (EC) No 1107/2009 of 21 October of the European Parliament and of the Council.

For the draft registration report a new template is available. This template has to be used for Core Assessments submitted as from 01.01.2016 except for product applications according to Art. 43 related to AIRII substances. The template can be downloaded from the [website](#) of the European Commission.

### **3 Effects on bees**

#### **3.1 Background**

"EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)" ([EFSA Journal 2013;11\(7\):3295](#))

Up to now there is no agreement to the implementation of the Guidance Document. However, the EU Commission created a road map showing which elements of the Guidance should be implemented at which point of time of application.

As recommended in the EFSA technical report (PRAS 133): "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" ([EFSA supporting publication 2015:EN-924](#)), the tier 1 of the risk assessment should be conducted according to the new EFSA Bee Guidance Document, in case the new data requirements according to Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 apply (which is for dossiers submitted after 1 January 2014). In case of contradictions between EFSA technical report (PRAS 133): "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" and "the roadmap", the technical report (PRAS 133) recommendations are followed.

For bees several different possibilities for exposure to a plant protection product exist:

- i. Exposure via contact (spray deposits, dust drift)
- ii. Consumption of pollen and nectar (treated crops, weeds in the field, plants in field margin, adjacent crops or succeeding crops/permanent crop)
- iii. Consumption of water (guttation water, surface water, puddles)
- iv. Risk from metabolites present in pollen and nectar

### **3.2 Choice of ecotoxicological endpoint**

In standard laboratory tests the following endpoints are in general derived for the active substance and established in the List of Endpoints (LoEP) of an active substance. The values from the LoEP provide the basis for the risk assessment:

- i. Acute oral and contact toxicity to bees: LD<sub>50</sub> [ $\mu\text{g}$  a.s./bee]
- ii. Chronic oral toxicity to bees: LDD<sub>50</sub> [ $\mu\text{g}$  a.s./bee/day]
- iii. Toxicity to larvae: NOEC [ $\mu\text{g}$  a.s./larvae/development period]

For the approval of plant protection products, in all cases the acute oral and contact toxicity have to be addressed as well. If the product contains more than one active substance or a safener ii and iii also have to be considered.

### **3.3 National risk assessment**

Currently there is no harmonization as regards the risk assessment for bees. National decisions and requirements are summarized in the following:

- i. EFSA (2013) should be used for products where the new data requirements apply. It is acceptable to provide a risk assessment according to EPPO; however, a risk assessment according to EFSA (2013) should also be conducted.
- ii. In case bumble bee or solitary bee data are available, a respective risk assessment according to EFSA (2013) should also be conducted. If such data are not available, this is acceptable (following the technical report (PRAS 133) recommendation).
- iii. For higher-tier risk assessment EFSA (2013) does not need to be strictly applied. In such a case a risk assessment, based on the data available and expert judgement is performed, taking into account also elements from EFSA (2013).
- iv. Generally it is recommended to perform studies with the product. However, in case active substance or solo formulation studies are available with all substances which show low toxicity and exposure is low, and there is no indication of higher acute toxicity of the product, waiving of additional studies in a case by case decision may be acceptable.
- v. Larvae study – single vs. repeated exposure: The multiple (repeated) exposure design including pupation is considered as more appropriate and such studies are requested for recent/future dossier submissions. This is in accordance with the recommendation of the COM roadmap. However, at the moment existing single dose studies are also accepted and their endpoints are used for risk assessment on a national level.

### **3.4 Risk mitigation measures**

In respect to reducing the risk of exposure to bees labelling of the product with SPe 8 is possible, e.g.:

“Dangerous to bees. To protect bees and other pollinating insects

- i. do not apply to crop plants when in flower or when flowering weeds are present.
- ii. Do not use where bees are actively foraging.”
- iii. ...

[ABKÜRZUNGSVERZEICHNIS](#)