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

Ecotoxicology
Bees

Information for notifier/applicants and other interested parties

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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.

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. 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).

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_{50} [µg a.s./bee]
ii. Chronic oral toxicity to bees: LDD_{50} [µg a.s./bee/day]
iii. Toxicity to larvae: NOED or ED_{10} [µg a.s./larvae/development period]

For the approval of plant protection products, acute and chronic toxicity have to be addressed with product studies in case

- the product contains more than one active substance or a safener **or**
- in case the toxicity of the product cannot be reliably predicted based on the active substance.

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.
ii. In case bumble bee or solitary bee data are available, a respective risk assessment according to EFSA (2013) should also be conducted. At the time being, such data are not strictly required (following the technical report (PRAS 133) recommendation).
iii. Studies according to OECD GD No. 239 (2016, repeated exposure, including pupation) should be submitted to address the data requirement for honeybee larvae.
iv. Studies with a comparable product may be considered for the assessment in a case-by-case decision.
v. For products containing more than one active substance the submission of toxicity data with the respective active substances or solo-products is not sufficient to address the risk to honeybees.
vi. In case required toxicity studies are missing, but an acceptable risk is indicated by the toxicity studies provided, labelling of the product will be considered.
vii. For higher-tier risk assessment an assessment based on the data available and expert judgement is performed, taking into account also elements from EFSA (2013) (following the technical report (PRAS 133) recommendation).

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. …

„Bienengefährlich. Zum Schutz von Bienen und anderen bestäubenden Insekten

i. nicht auf blühende Kulturen aufbringen.
ii. Nicht an Stellen anwenden, an denen Bienen aktiv auf Futtersuche sind."
iii. …

In case the data requirements are not fulfilled but a low risk to honeybees can be assumed based on the available data the following labelling of the product is considered.

"An application in flowering plant stocks (crops and weeds) is only permitted between the end of the daily bee flight and 11 p.m."

"Im Fall von Anwendungen in blühenden Pflanzenbeständen (Kulturpflanzen, Unkräuter) darf die Anwendung nur nach dem Ende des täglichen Bienenflugs bis 23:00 Uhr erfolgen."

Abbreviations

ED_{10}	Effect dose 10 %
EFSA	European Guidance Document food safety authority
GD	Guidance document
LD_{50}	lethal dose 50 %
LDD_{50}	lethal dietary dose 50 %
LoEP	list of endpoints
NOED	no observed effect dose