

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

Ecotoxicology Non-target Terrestrial Plants (NTTP)

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 non-target terrestrial plants** 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.

7 Effects on non-target terrestrial plants

7.1 Background

The risk assessment for non-target terrestrial plants has to be conducted according to the EC terrestrial guidance document ([SANCO/10329/2002 rev 2 final](#)).

7.2 Choice of ecotoxicological endpoint

A tiered approach is suggested starting with available data and proceeding to further steps if required. Data are not required, where exposure is negligible, e.g. in the case of rodenticides, substances used for wound protection or seed treatment, or in the case of substances used in stored products or in glasshouses.

Tier 1: Initial decision on the likelihood for terrestrial plant effects

This assessment step is based on initial screening data. As a general rule, the risk should be considered acceptable if there are no data indicating more than 50 % phytotoxic effect at the maximum application rate. If the results show more than 50 % effect for one species or clear indications of effects on more than one species, data requirements and assessment move to the next tier.

For products with 2 or more a.s., the selection of tested species should include the species which were most sensitive to the individual a.s..

Tier 2: Quantitative risk assessment

This tier is a quantitative risk assessment following a TER approach. Effects data are represented by ER₅₀ values from the studies. There are two options, a deterministic and a probabilistic approach, from which a choice should be made with regard to the data set.

Deterministic approach:

If the TER based on the most sensitive species is greater than 5 effects on non-target plants are considered acceptable. This trigger of 5 presupposes that at least 6 species have been tested. The trigger may be reduced if information on more species is available.

Probabilistic approach:

Probabilistic methods that make use of the species sensitivity distribution can be used in this assessment step if data from 6-10 species are available. If the ED₅₀ for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable.

7.3 Higher tier risk assessment

The higher tier risk assessment (Tier 3) is based on (semi-)field studies. A higher tier risk characterisation and therefore, a case-by-case analysis is required at this stage.

7.4 National risk assessment

The national risk assessment is fully in line with the current EU approach.

7.5 Risk mitigation

In respect to the assessment the following mitigations measures may be applied:

- i. Reduction of the application rate
- ii. Reduction of pesticide input via spray drift by applying drift reducing nozzles with an efficiency of 50, 75, and 90 % (the latter reducing drift to 95 % when combined with hail protection nets in orchards and vines)
- iii. Reduction of pesticide input via spray drift by applying drift reducing nozzles with an efficiency of 90 % (the latter reducing drift to 95 % when combined with hail protection nets in orchards and vines) in combination with a 5 meter in-field unsprayed buffer zone.

[ABKÜRZUNGSVERZEICHNIS](#)