

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

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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 the 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 notifiers/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 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.

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](#)) and under consideration of the relevant part "6. Non-target terrestrial plants" in EFSA Supporting publication 2019:EN-1673. The exposure assessment of terrestrial plants uses as surrogate the drift models produced by the BBA for the exposure assessment of aquatic organisms (Ganzelmeier *et al.* 1995, later updated by Rautmann *et al.* 2001).

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. There should be at least 6 species from different taxa tested. 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.

Tier 2: Quantitative risk assessment

This tier is a quantitative risk assessment following a TER approach. Dose-response tests on 6 – 10 plant species of different taxa should be provided, where it should be avoided to include a high number of insensitive species. Effect data are represented by ER₅₀ values from the studies. There are two options, a *deterministic* and a *probabilistic* approach, the choice should be made with regard to the available data set.

Deterministic approach:

If the TER based on the most sensitive NTTTP species is greater than the trigger value of 5, effects on non-target plants are considered acceptable. This trigger of 5 presupposes that at least 6 species have been tested.

Probabilistic approach:

Probabilistic methods that make use of the species sensitivity distribution (SSD) can be used in this assessment step if data from 6-10 plant species are available. If the ER₅₀ for less than 5 % (often referred to as HR₅) of the NTTTP species is below the highest predicted exposure level (PER), the risk for terrestrial plants is assumed to be acceptable (i.e. HR₅/PER > 1).

7.2 Choice of ecotoxicological endpoint

For the choice of endpoints aside of the standard endpoints listed in the NTTTP test guidelines also visual phytotoxicity must be considered if present in the available studies (see "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" EFSA Supporting publication 2019:EN-1673, page 26).

For products (with one or more a.s.) the selection of tested species in the provided effect studies should include the NTTTP species which were most sensitive to the individual a.s. according to the active substance evaluation.

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 risk assessment the following risk mitigation measures may be applied in Austria:

- 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.

7.6 Abbreviations

a.s.	Active substance
AIR-II	Annex I Renewal, stage II
dRR	draft Registration Report
ER ₅₀	Effect Rate causing 50% effect

HR ₅	Hazardous Rate, 5 th percentile
NTTP	Non-target terrestrial plants
PER	Predicted exposure rate
PPP	Plant protection product
SSD	Species sensitivity distribution
TER	Toxicity/Exposure ratio