

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

Ecotoxicology Non-target Arthropods (NTA)

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 non-target arthropods** 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.

4 Effects on non-target arthropods other than bees

4.1 Background

The risk assessment for non-target arthropods has to be conducted according to the "Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods (ESCORT II Workshop, 2000), 2001" and the EC terrestrial guidance document ([SANCO/10329/2002 rev 2 final](#)).

For non-target arthropods the hazard evaluation at Tier I is based on a hazard quotient (HQ) approach. The HQ is derived from the crop-specific application rates for in-field assessments or drift rates for off-field scenarios and the LR₅₀ value generated with the standard testing species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. In case of solid formulations soil dwelling species have to be tested (e.g. *Aleochara bilineata*, *Pardosa* sp.)

For the standard species in the tier 1 risk assessment the Predicted Environmental Rate is calculated as PER_{foliar}. In higher tier, soil dwelling arthropods may become relevant and for this species PER_{soil} has to be calculated. For multiple applications Multiple Application Factors (MAF) for foliar and soil dwelling organisms, respectively, are provided in the ESCORT II guidance document.

For non-target arthropods the in-field risk due to direct application and the off-field risk due to spray drift have to be addressed properly.

To consider structural conditions in the off-field risk assessment, a vegetation distribution factor of 10 is applied. Please note that according to "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" (EFSA Supporting publication 2019:EN-1673) on page 24 a vegetation

distribution factor of 5 should be used upon an agreement of the experts that the original vegetation distribution factor might not be fully appropriate in the light of current knowledge. However, until this recommendation is implemented on a legal basis the national assessment in Austria will be conducted with the original vegetation distribution factor of 10. In higher tier tests, this vegetation distribution factor is depending on the mode of the testing (a factor of 10 for 2-D testing with application of the test substance on detached leaves or a factor of 1 for 3-D testing, application of the test substance to whole plants).

Furthermore a correction factor of 10 is added to the off-field risk assessment to account for uncertainty with the extrapolation from *T.pyri* and *A. rhopalosiphi* as indicator species, to all off-field non-target arthropods. If more than the two standard species have been tested, the factor can be reduced to 5.

4.2 Choice of ecotoxicological endpoint

In standard laboratory tests conducted with plant protection products the focus is on the derivation of LR₅₀ values whereas in higher tier studies (e.g. extended laboratory studies, field studies,...) also reproduction or other sublethal effects are considered and an ER₅₀ is derived.

4.3 Higher tier options

For higher tier testing the following options are given:

- i. Extended laboratory test: If testing with the standard species indicates a high in-field risk for one or both of the indicator species, this species and one additional species have to be tested in extended laboratory tests.
If also a high off-field risk is indicated, two additional species to the standard species shall be tested in extended laboratory tests.
- ii. Aged residue test: These studies are designed to assess the duration of effects of a plant protection product to non-target arthropods. This test may be used to show the potential for recovery and possible re-colonization in the field.
- iii. Semi-field studies: These studies are single-species tests where both the test system (treated plants) together with the test organisms initially are maintained in the field, usually under partly controlled conditions.
- iv. Field studies: determination of short- and long-term effects of a test substance applied under normal agricultural conditions according to the proposed use pattern on naturally occurring arthropod populations. They can be targeted on key species and/or on specific arthropod groups identified from the lower tier testing/risk assessment to be at risk and/or to the whole fauna community. The potential for re-colonization/recovery should be one of the key questions to be addressed in field tests.

4.4 National risk assessment.

The national risk assessment is generally in line with the current EU approach. However, some member states deal with different situations in different ways. Therefore the Austrian decisions are presented in the following:

- i. In case no standard laboratory data are available (only extended laboratory studies) two additional arthropod species always have to be tested as it has to be assumed that the Tier 1 trigger is not met for in- and off-field. This means that extended laboratory studies with *A. rhopalosiphi* and *T. pyri* and two additional species are required.
- ii. In case a high in-field risk was identified an aged residue study with all at least the most sensitive species have to be submitted to address the risk. In case residue trials are available the refined DT₅₀ can be used to address the risk. Taking into account the degradation of the substance the potential for re-colonisation of the arthropods can be estimated. However, this approach is only valid if acceptable (covering the specific conditions of the GAP) residue trials are available. Otherwise an aged residue test or further residue trials have to be submitted.

4.5 Risk mitigation measures

The following risk 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 unsprayed in-field buffer zone.

In 2015 a Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods ([EFSA Journal 2015;13\(2\):3996](#)) was published. Currently a new guidance document for the risk assessment of non-target arthropods is in progress.

Abbreviations

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|------------------|--------------------------------|
| AIR | Annex I Renewal |
| DT ₅₀ | degradation time |
| EFSA | European Food Safety Authority |
| ER _x | Effect rate |
| HQ | hazard quotient |
| GAP | good agricultural practice |
| LR _x | lethal rate |
| MAF | multiple application factor |
| PER | predicted environmental rate |