

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

Ecotoxicology Aquatic Organisms

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 aquatic organisms** 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.

2 Risk assessment for aquatic organisms

2.1 Background

The risk assessment for aquatic organisms has to be conducted according to the Guidance Document on Aquatic Ecotoxicology (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. [EFSA Journal 2013; 11\(7\):3290, 268pp. doi: 10.2903/j.efsa.2013.3290](#) – to be used for application after 1.1.2016.

The aquatic risk assessment for plant protection products in edge-of-field surface waters is based on the proper linkage of predicted exposure concentrations (time-dependent concentrations in different compartments of the environment calculated by the environmental fate section) to ecotoxicological data. The risk assessment follows a stepwise approach using different tiers.

The ecotoxicological data usually concern concentration - response relationships derived from controlled experiments with standard species (tier 1), additional aquatic test species (tier 2) or micro-/mesocosm tests (tier 3). Assessment factors and/or modelling approaches, are used to extrapolate the experimental concentration - response relationships in space and time, e.g. to estimate the threshold concentrations for toxic effects in the field.

2.2 Predicted environmental concentration in the surface water and sediment (PEC_{SW} and PEC_{SED})

For detailed information about calculating predicted environmental concentration in the surface water and sediment please refer to [eFate National Exposure Assessment Requirements](#).

The FOCUS surface water working group defined 10 realistic worst-case surface water scenarios for the aquatic exposure assessment at the EU level (FOCUS, 2001). In general, exposure of pesticides to surface water bodies is assumed to be governed by direct input via spray drift during application as well as indirect input via soil surface runoff, erosion and drainage. In respect to these input pathways the FOCUS surface water scenarios are intended to represent realistic worst-case conditions (90th percentile vulnerability in space and time). In the FOCUS surface water scenarios only small water courses (stream and ditches) with a width of 1 m and a depth of 0.3 m are accounted for as well as small ponds (30m x 30m x 1m).

2.3 Choice of ecotoxicological endpoint

Standardized testing procedures lead to the below mentioned ecotoxicological endpoints which are established in the List of End Points (LoEP) of an active substance. The values from LoEP provide the basis for the risk assessment:

- i. Fish:
LD₅₀ for acute toxicity, NOEC for long-term toxicity [mg a.s./L]
- ii. Aquatic invertebrates:
EC₅₀ for acute toxicity, NOEC for long-term toxicity [mg a.s./L]
- iii. Algae:
EC₅₀ based on growth rate (E_rC₅₀) and based on biomass (E_bC₅₀; E_yC₅₀) for long-term toxicity [mg a.s./L]
- iv. Aquatic Macrophytes:
EC₅₀ based on growth rate (E_rC₅₀) and based on biomass (E_bC₅₀; E_yC₅₀) for long-term toxicity [mg a.s./L]

For the authorisation of a plant protection product, studies with the respective formulation have also to be provided. The data requirements therefore are set in the Commission Regulation (EU) No 284/2013. Attention has to be paid to whether the endpoint should be expressed as nominal or mean measured concentration, pending on whether the concentration is maintained ± 20% of the nominal throughout the test or not. For further information regarding the calculation of how to express the endpoint adequately please refer to the EFSA technical report: "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" ([EFSA supporting publication 2015:EN-924](#)).

2.4 Regulatory acceptable concentration (RAC)

The regulatory acceptable concentration is derived from the approved ecotoxicological endpoint and directly compared with the relevant predicted environmental concentration.

According to the new aquatic GD the RAC can be derived on the basis of two options:

The ecological threshold option (ETO), accepting negligible population effects only, and the ecological recovery option (ERO), accepting some population-level effects if ecological recovery takes place within an acceptable time period.

In principle, all the tiers are able to address the ETO, while only higher tiers may be able to address also the ERO. The tier 1 RAC are based on standard toxicity endpoints; the tier 2 RAC are based on

the standard and additional single species laboratory tests to calculate the geometric mean or to construct a species sensitivity distribution (SSD) curve or on refined exposure tests; while the tier 3 RAC are based on the microcosm and/or mesocosm data.

However, during the harmonization process of the central zone member states, it was decided to only use the ETO in the risk assessment.

2.5 Mixture toxicity (Combinations of active substances in formulations)

The Regulation (EC) No 1107/2009 requires that "interaction between the active substance, safeners, synergists and co-formulants shall be taken into account" in the evaluation and authorisation. Furthermore, the standard data requirements for plant protection products (Commission Regulation (EU) No 284/2013) do request "any information on potentially unacceptable effects of the plant protection product on the environment, on plants and plant products shall be included as well as known and expected cumulative and synergistic effects."

The mixture toxicity is addressed in the Aquatic Guidance Document [EFSA Journal 2013; 11\(7\):3290](#).

2.6 Higher tier options

The Aquatic Guidance Document [EFSA Journal 2013; 11\(7\):3290](#) provides several options for risk assessment refinements:

- i. Considering additional studies from the open literature
- ii. Testing additional species
- iii. Geometric mean AF-approach
- iv. Species sensitivity distribution (SSD) approach
- v. Modified exposure studies
- vi. Model ecosystem experiments (micro-/mesocosm studies)

2.7 National risk assessment

The national risk assessment is largely in line with the current EU approach. However, there are some national specifications which might deviate from the EU approach:

- i. In case that in the core assessment FOCUS step 3 calculations were not sufficient to demonstrate a safe risk a risk assessment with FOCUS step 4 PEC_{sw} values has to be provided on a national level.
- ii. However if the use pattern for the national application is different to the use pattern evaluated in the core assessment it may be necessary to provide a complete risk assessment adapted to the national use in order to determine the relevant national risk mitigation measures.

2.8 Risk mitigation measures

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

- i. Reduction of the application rate
- ii. Reduction of pesticide input via spray drift by combination of increasing the distance between the treated field and the top of the bank of the water body to 5, 10, 15 or 20 m assuming 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 runoff and erosion by introducing a vegetated unsprayed buffer zone of 5, 10, 15 or 20 m
- iv. Restrictions regarding areas vulnerable to runoff. This will be the case if safe use conditions cannot be demonstrated for the FOCUS surface water scenarios accounting for runoff (R1 or R3) following runoff mitigation. This will lead to the labelling 'To protect aquatic organisms from run-off in surface water do not apply on run-off endangered areas.

[ABKÜRZUNGSVERZEICHNIS](#)