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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.

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. Furthermore, updates published in the EFSA technical reports: "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" should be considered where applicable (EFSA supporting publication 2015:EN-924 and EFSA supporting publication 2019:EN-1673).

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 the sediment (PEC_{SW} and PEC_{SED})

For detailed information about calculating predicted environmental concentration in the surface water and the 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 (90^{th} 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 endpoints (LoEP) of an active substance. The values from LoEP provide the basis for the risk assessment:

i. Fish:
   LC_{50} for acute toxicity, NOEC and EC_{10} for long-term toxicity [mg a.s./L]
ii. Aquatic invertebrates:
   EC_{50} for acute toxicity, NOEC and EC_{10} for long-term toxicity [mg a.s./L]
iii. Algae:
   EC_{50}, NOEC and EC_{10}based on growth rate (E_rC_x) and based on biomass (E_bC_x; E_yC_x) for long-term toxicity [mg a.s./L]
iv. Aquatic Macrophytes:
   EC_{50}, NOEC and EC_{10} based on growth rate (E_rC_x) and based on biomass (E_bC_x; E_yC_x) 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. All endpoints expressed as EC_{10} values (long-term toxicity) should be checked for reliability based on the concept of the confidence interval. Attention has to be paid to whether endpoints 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. Tests conducted in the presence of sediment (e.g. with *Chironomus riparius*) require analytical measurements of (i) the sediment, (ii) the pore water and (iii) the overlying water in order to assess the behaviour/partitioning of the chemical in the water-sediment system (via mass balance calculation). The endpoints from such tests should be presented in terms of both, mg a.s./kg dry sediment and mg a.s./L water. For further information regarding adequate endpoint calculations, please refer to the EFSA technical reports: "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (EFSA supporting publication 2015:EN-924 and EFSA supporting publication 2019:EN-1673).

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 Aquatic Guidance Document, 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 RACs are based on standard toxicity endpoints; the tier 2 RACs 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 RACs 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 ETO-RACs 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. Furthermore, it is noted that a tool for the calculation of aquatic mixture toxicity according to the Aquatic Guidance Document was developed as an initiative of regulators from different member states, that can be downloaded here.

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)

With regard to the geometric mean AF-approach (iii.), reference is made to the EFSA supporting publication 2019:EN-1673, where further considerations on the selection of an appropriate AF for acute data can be found. The use of the geometric mean AF-approach for combining chronic data is currently not supported.
Considering the higher tier option of modified exposure studies (v.) it is noted that the use of time weighted average surface water PECs ($PEC_{SW,\ TWA}$) is unlikely to be sufficiently robust for a use in regulatory risk assessment until further guidance on reciprocity and latency of effects are available (EFSA supporting publication 2015:EN-924).

2.7 National risk assessment

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

i. In case that in the core assessment FOCUS step 3 calculations were not sufficient to demonstrate an acceptable risk, a risk assessment with FOCUS step 4 PEC_{sw} values has to be provided on 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 % (efficiency of 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 an acceptable risk cannot be demonstrated for the FOCUS surface water scenarios accounting for runoff (R1 or R3) following runoff mitigation. The restriction will lead to the labelling 'To protect aquatic organisms from run-off in surface water do not apply on run-off endangered areas'.

ABKÜRZUNGSVERZEICHNIS

AF	Assessment factor
a.s.	Active substance
AIR-II	Annex I Renewal, stage II
E_bC_x	Half maximal (X%) effect concentration related to biomass growth
EC_X	Effect concentration (X%)
EFSA	European food safety authority
E_rC_x	Half maximal (X%) effect concentration related to growth rate
ERO	Ecological recovery option
ETO	Ecological threshold option
E_yC_x	Half maximal (X%) effect concentration related to inhibition of yield
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GD	Guidance document
LC_X	Lethal concentration (X%)
LoEP	List of endpoints
NOEC	No observed effect concentration
PEC_{SED}	Predicted environmental concentration in sediments
PEC_{SW}	Predicted environmental concentration in surface waters
$PEC_{SW, TWA}$	Time weighted average of the predicted environmental concentration in surface waters
PPP	Plant protection products
RAC	Regulatory acceptable concentration
SSD	Species sensitivity distribution