Bundesamt für Ernährungssicherheit (BAES)
p.A. Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)
Spargelfeldstraße 191, 1220 Vienna, Austria

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

Ecotoxicology
Non-target Soil 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 non-target soil 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.

5 Effects on earthworms and other soil non-target macro organisms

5.1 Background

The risk assessment for earthworms and other soil non-target macro-organisms has to be conducted according to the EC terrestrial guidance document (SANCO/10329/2002 rev 2 final).

According to the currently valid data requirements (Commission Regulation (EU) No 283/2013 and (EU) No 284/2013 of 1 March 2013), sublethal testing of earthworms is required.

For plant protection products applied as a foliar spray, data on the relevant two non - target arthropod species might be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required.

For plant protection products applied as soil treatments directly to soil either as a spray or as a solid formulation, testing shall be required on both *Folsomia candida* and *Hypoaspis aculeifer.*

The exposure is represented by the initial predicted in-field concentration of the substance in soil (PEC_{soil}). In case of repeated applications, the PEC after the last application is relevant. In case of persistent substances the plateau concentration is relevant.

5.3 Predicted environmental concentration in the soil (PEC_{soil})

For detailed information about calculating predicted environmental concentration in the soil please refer to **eFate National ExposureAssessment Requirements.**

At EU level the soil exposure assessment for active substances is currently based on the outcome of the soil modelling work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their Use) (FOCUS, 1997). In short, PEC values in soil for parent and metabolites are usually based on simple spread sheet calculations assuming uniform distribution in the soil (uppermost 5 cm) with a soil density of 1.5 kg/L. No processes other than degradation/dissipation (DT_{50}) are accounted for.

5.4 Choice of ecotoxicological endpoint

Standard laboratory testing with earthworms and other soil non-target organisms in general provides a dose-response relationship and an EC_{10}, EC_{20} and NOEC. Endpoints derived for the active substance are established in the List of Endpoints (LoEP). Testing with the formulation incorporated into soil is generally required if the formulation contains more than one active substance or of the toxicity of the formulation cannot be predicted on the basis of data for the active substance

According to the Technical Report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology (EFSA supporting publication 2015:EN-924), the endpoint should be divided by a factor of 2 if the log P_{ow} of the substance is > 2. For formulations with more than one active substance the product endpoint has also to be corrected by a factor 2 if the log P_{ow} of one of the active substances is > 2.
This approach results from the assumption that that bioavailability for soil organisms of lipophilic substances could be reduces in order of different soil characteristics.

For higher tier or refined studies, it was considered potentially feasible to perform a range of studies with various amounts of organic material to demonstrate that the toxicity is independent of the organic material content of the soil.

5.5 Higher tier options

For higher tier testing a soil organisms field study can be conducted. The study is required where TER_{lt} is < 5. The study should reflect the use of the compound, the environmental conditions and species that will be exposed. If the chemical is to be applied in the arable situation it should preferably be applied to bare soil as opposed to grassland where it may become bound to the surface thatch. Analysis of the soil would assist in confirming whether the field study is appropriate for the intended arable crop use. With regard to the dosage the test should be designed in order to cover the highest exposure according to the intended use of the product. That means that multiple applications should be made where relevant, and crop interception should be considered. If accumulation in soil is expected then a rate equivalent to the long-term (plurennial) plateau concentration should be added. The type of application of the test substance (surface application, incorporation, etc.) should be according to the intended use.

A method is described by ISO (11268-3:1999). For further information see also Greig-Smith et al. (1992)[1], Sheppard et al. (1997)[2], de Jong (2006)[3] and EFSA Supporting publication (2019)[4].

5.6 National risk assessment

[1] Greig-Smith PW, Becker H, Edwards PJ and Heimbach F (Eds.) (1992): Ecotoxicology of earthworms. Intercept, Andover UK.
[2] Sheppard SC, Bembridge JD, Holmstrup M and Posthuma L (Eds.) (1997): Advances in earthworm ecotoxicology. SETAC Press
[3] de Jong F.M.W., van Beelen P., Smit C.E. and Montforts M.H.M.M. (2006): A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies – Guidance for summarizing earthworm field studies
[4] "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" EFSA Supporting publication 2019:EN-1673.

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

- Formulation toxicity expressed in terms of active substance content should be compared with the PEC_{soil} for the active substances.

5.7 Risk mitigation

Risk mitigation options for earthworms and other soil macro-organisms are limited. Reduction of the application rate is possible.

6 Effects on soil microbial activity

6.1 Background

The risk assessment for soil micro-organisms has to be conducted according to the EC terrestrial guidance document (SANCO/10329/2002 rev 2 final).

According to the currently valid data requirements (Commission Regulation (EU) No 283/2013 and (EU) No 284/2013 of 1 March 2013), soil nitrogen transformation testing is required.

The ecotoxicological endpoint is directly compared with the predicted exposure concentration for soil (PEC_{soil}).

6.2 Predicted environmental concentration in the soil (*PEC_{soil}*)

For detailed information about calculating predicted environmental concentration in the soil please refer to **eFate National ExposureAssessment Requirements.**

At EU level the soil exposure assessment for active substances is currently based on the outcome of the soil modelling work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their Use) (FOCUS, 1997). In short, PEC values in soil for parent and metabolites are usually based on simple spread sheet calculations assuming uniform distribution in the soil (uppermost 5 cm) with a soil density of 1.5 kg/L. No processes other than degradation/dissipation (DT_{50}) are accounted for.

6.3 Choice of ecotoxicological endpoint

Endpoints for the active substance and their metabolites are listed in the List of End Points (LoEP) of an active substance. The values from the LoEP provide the basis for the risk assessment, however in general testing with the formulation is required if the toxicity of the formulation cannot be predicted on the basis of data for the active substance.

The decisive parameter is the magnitude of effect compared to the untreated control, no matter if it is an increase or a decrease of activity, and the time-course of recovery. The critical level is set at ±25% effect after 100 days.

The test concentrations have to be compared directly with the predicted exposure concentration for soil (PEC_{soil}).

6.4 National risk assessment

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

6.5 Risk mitigation measures

Risk mitigation options for soil micro-organisms are limited. Adaptation of the GAP (e.g. number of applications, interval between applications, time of application (interception)) is possible or restriction on glasshouse use only.

ABKÜRZUNGSVERZEICHNIS

AIR	Annex I Renewal
DT_{50}	Degradation time
EC_x	Effect concentration
FOCUS	FOrum for the Co-ordination of pesticide fate models and their Use
LoEP	List of endpoints
NOEC	No observed effect concentration
PEC_{soil}	Predicted environmental concentration in soil
P_{ow}	Octanol-water partition coefficient
TER	Toxicity exposure ratio