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

Ecotoxicology
Birds & Mammals

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 birds and mammals** 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.

1 Risk assessment for birds and mammals

1.1 Background

The risk assessment for birds and mammals has to be conducted according to the EFSA Guidance for Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438, 17 December 2009).

The risk assessment for birds and mammals is based on the Toxicity-Exposure Ratio (TER) approach comprising three tiers.

Screening Step: This step aims to highlight those substances that do not require further consideration as their associated uses pose a low risk. This step uses an "indicator species" which is not a real species but, by virtue of its size and feeding habits is considered to be a worst-case model, assuming a high food intake rate, and consumption of one type of food which in turn has high residues on/in it.

Tier 1 risk assessment: The exposure is calculated via the intake of contaminated food for "generic focal species", which are still not real species but are considered to be representative of all those species potentially at risk, assuming a high food intake rate and probable consumption of a mixed diet based on ecological knowledge of a range of species that could be at risk.

Tier 2 risk assessment: The Tier 1 assumptions can be refined to by using data published in the scientific literature or rather determined experimentally, e.g. usage of "focal species" which actually occur in the crop when the pesticide is being used.

1.2 Choice of ecotoxicological endpoint

The assessment of the impact caused by acute exposure is based on the lowest of the LD_{50} values for oral intake or the geomean of several studies if applicable. The assessment of the impact caused by long-term exposure is based on the NOEC (No Observed Effect Level). EU approved (ecologically relevant) endpoints are established in the List of Endpoints (LoEP) of an active substance. The values included in the official LoEP provide the basis for the risk assessment. According to the new data requirements (Regulation (EU) No 283/2013 and (EU) No 284/2013), LD_{10} and LD_{20} shall be reported as well. A refinement of EU agreed endpoints is not acceptable.

For birds, the Guidance Document includes an assessment of the lethal effects caused by both acute exposure (gavage) and short-term exposure (dietary) over a period of a few days. Toxicity data from a 5-day feeding study (expressed as daily dose, dietary LD_{50}) are relevant for the latter. This short-term endpoint is only used for the risk assessment in case it is lower than the acute LD_{50} and not a greater than value.

According to the Commission Regulation (EU) No 284/2013 for the approval of a plant protection product, studies with the respective formulation on birds have to be provided if the toxicity cannot be predicted on the basis of the data for the active substance, or where results from the mammalian toxicological testing give evidence of higher toxicity of the plant protection product compared to the active substance.

1.3 Screening Step and Tier 1 Risk assessment

The daily dietary dose (DDD) is defined by the food intake rate of the species of concern (e.g. the indicator species, the generic focal species or the focal species), the body weight of the species of concern, the concentration of a substance in/on fresh diet and the fraction of diet obtained in the treated area. For this parameters respective shortcut values are provided in the EFSA Guidance for Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

The respective LD_{50} or NOEC is set into relation to the DDD. The resulting TER is compared with the respective trigger values established in the uniform principles (Commission Regulation (EU) No 545/2011 and Commission Regulation (EU) No 546/2011).

1.4 Secondary poisoning

According to the EFSA Guidance for Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438) a log $K_{ow} \geq 3$ indicates a potential for bioaccumulation. If this condition is met, the food chain from earthworm to earthworm-eating, as well as the food chain from fish to fish-eating birds and mammals should be considered for active substances and/or their metabolites. Furthermore the potential for biomagnification should also be considered.

i. For the risk assessment for earthworm-eating birds and mammals the predicted environmental concentration in soil (PECsoil) is required. For non-persistent substances the $PECsoil,21d_{twa}$, for persistent substances the $PECsoil,21d_{twa}$ + the plateau PECsoil is used. For detailed information about calculating predicted environmental concentrations in the soil, please refer to **eFate National ExposureAssessment Requirements**.
The EFSA Guidance for Risk Assessment for Birds and Mammals presents two approaches, the dry soil approach and the pore water approach to estimate the risk for earthworm-eating birds and mammals. According to the Harmonisation Work shop 2015, the risk assessment should currently be based on the dry soil approach only.
ii. For the risk assessment for fish-eating birds and mammals in general the RAC-aqua is used. For detailed information regarding the **RAC**, please refer to document "Risk assessment for Aquatic organisms, point 2.4 Regulatory acceptable concentration.

1.5 Risk through drinking water

Exposure of birds or mammals via drinking water is not explicitly included in the DDD calculations of the dietary risk assessment and has therefore to be considered separately. Due to the characteristics

of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary, when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/Kg).

If this "escape clause" does not apply, the risk assessment should be based on the EFSA calculation scheme. The risk for vertebrates through drinking water has to be conducted for each crop (puddle and/or leaf scenario). In general, the puddle scenario is required for all spray applications.

The MAFm value used in the drinking water risk assessment should be calculated considering the soil DT_{50} value. The geomean DT_{50} soil (used in the environmental fate section for the calculation of the PECgw and PECsw) should be used.

1.6 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."

Applications submitted after 15.06.2016, have to address the acute and long-term combined toxicity for birds and mammals.

1.7 Higher tier options

In the higher tier risk assessment various parameters may be refined based on data derived from scientific literature and experimental data, respectively.

i. Re-assessment of the exposure period relevant to the toxicity endpoints: The use of the default averaging interval (21 d) is acceptable for single application however in case of multiple applications it might underestimate the risk. A re-calculation of the ftwa (time weighted average factor) and the MAF (Multiple application factor) should be based on the intended application interval with the time moving window approach.
ii. Refinement of the RUD (residue unit dose) is considered not acceptable by most experts, especially for grass and weeds, as the database of the EFSA GD is quite large.
iii. Refinement of residue decline should follow the recommendations of "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" EFSA Supporting publication 2019:EN-1673.
iv. The DDD may be refined by using more relevant data on the ecological components of the risk assessment like Focal Species, proportion of an animal's daily diet obtained in habitat treated with pesticide (PT) and composition of diet obtained from treated area (PD). According to the Harmonisation Workshop Wageningen (2014) the PT value should always be based on the 90th percentile PT (consumers only) derived from field data. Refinements of PT and PD values are solely applicable to long-term DDD´s.

1.8 Risk assessment for granular formulations

For granular formulations the risk assessment is different than for spray applications. It is possible that birds and mammals may be exposed to granules in different ways (EFSA Journal 2009; 7(12):1438, 17 December 2009).

i. Birds and mammals may ingest granules as a source of food
ii. Birds may ingest granules as grit
iii. Birds may mistake granules for small seed.

iv. Birds and mammals may ingest granules when they eat food contaminated with soil
v. Birds and mammals may consume food contaminated with residues resulting from granular applications.

However, for the ingestion of granules as DGritD or DGD a correction is necessary: According the EPPO risk assessment (see EPPO 2003), for DGritD a small bird is 25 g and a large bird is 300 g. According the EFSA risk assessment, for DGD granivorous bird is 15.3 g. It is important that the DGritD and DGD figures are corrected to bird size (or normalized to kg body weight) before calculating TERs (the acute TER could be underestimated by a factor of 40 without this correction).

1.9 Seed treatments

For treated seeds the risk assessment is different than for spray applications. Tier 1 assumes that granivorous birds and mammals feed entirely on readily available, freshly treated seeds.

The choice of the indicator species depends on the size of the seeds. For systemic products an additional scenario of birds and mammals feeding on crop seedlings should be considered in the risk assessment as it is possible that birds and mammals may consume seedlings that contain residues of the active substance or consume the seedling and the remaining seed.

1.10 National risk assessment

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

i. Focal species are country specific - the determination of the relevant focal species and their ecological parameters should be based on generic field data which is relevant for Austrian conditions.
ii. Residue data are region specific and should be relevant for Austrian conditions.

1.11 Risk mitigation measures

The following risk mitigations measures may be applied:

i. Reduction of the application rate
ii. Reduction/adaption of application window
iii. Risk phrase (not during bird breeding period/nicht während Brutzeit, product must be entirely incorporated in the soil/Mittel muss eingearbeitet werden (Saatgut), remove spillages/verschüttetes Mittel muss beseitigt werden, etc.)

Abbreviations

AIR	Annex I Renewal
DDD	daily dietary dose
DGD	daily granule dose
DGritD	daily grit dose
DT_{50}	degradation time
EFSA	European Food Safety Authority
ftwa	time weighted average factor
K_{oc}	organic carbon absorption coefficient
LoEP	list of endpoints

MAF	multiple application factor
NOEC	no observed effect concentration
PD	composition of diet obtained from treated
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surfacewater
PT	proportion of animals daily diet obtained in habitat treated with pesticide
RAC	regulatory acceptable concentration
TER	toxicity exposure ratio
twa	time weighted average