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

Ecotoxicology

Information for notifier/applicant 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 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 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.

In addition to the above mentioned regulations, the following publications and manuals are followed at zonal and national level, except otherwise stated.

i. 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).
ii. Outcome of the Central Zone Harmonisation Workshops (Central Zone Evaluation Manual – Ecotoxicology (available in the public folder on CIRCABC)

Table of Contents

1 Birds & Mammals

1.1 Risk assessment for birds and mammals

1.1.1 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 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.

1.1.2 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.

1.1.4 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 these 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).

1.1.5 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 (PEC_{soil}) is required. For non-persistent substances the PEC_{soil},$21d_{twa}$, for persistent substances the PEC_{soil},$21d_{twa}$ + the plateau PEC_{soil} is used. For detailed information about calculating predicted environmental concentrations in the soil, please refer to eFate National Exposure Assessment 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 Workshop 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.

1.1.6 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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ 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 MAF_m 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 PEC_{gw} and PEC_{sw}) should be used.

1.1.8 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.

1.1.9 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 f_{twa} (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.

1.1.10 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 normalised to kg body weight) before calculating TERs (the acute TER could be underestimated by a factor of 40 without this correction).

1.1.11 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.

1.1.12 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.

1.2 Risk mitigation measures

i. The following risk mitigations measures may be applied:
ii. Reduction of the application rate
iii. Reduction/adaption of application window
iv. Risk phrases (e.g. SPe 5, SPe 6, etc.)

2 Aquatic organisms

2.1 Risk assessment for aquatic organisms

2.1.1 Background

The risk assessment for aquatic organisms has to be conducted according to the Guidance Document on Aquatic Ecotoxicology (EFSA Journal 2013; 11(7):3290).

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.

2.1.3 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).

2.1.4 Choice of ecotoxicological endpoint

Standardised 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 (2015 and 2019). With regard to acute toxicity fish tests with formulations it is noted that the threshold approach (OECD 126) or a limit test (according to OECD 203) might be considered instead of a full dose-response test in order to minimise vertebrate testing in fish. For more details on the circumstances under which a full dose-response test is not necessary, reference is also made to the latest version of the CZ Evaluation Manual – Ecotoxicology (available in the public folder on CIRCABC).

2.1.6 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 harmonisation process of the central zone member states, it was decided to only use ETO-RACs in the risk assessment.

2.1.7 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. The latest version can be downloaded here.

The respective dRR template which is recommended to be used for the mixture toxicity assessment can also be obtained from the zenodo platform. Moreover, applicants are asked to submit the filled-out mixture toxicity excel files (in a zip folder) along with the dossier submission.

2.1.8 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).

2.1.9 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.

2.2 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'.
v. Restriction to areas without drainage. Only applicable when a safe use cannot be demonstrated under consideration of the maximum mitigation measures for FOCUS Scenario D4. In this case, PEC_{sw} values for FOCUS Scenario D4 can be calculated without consideration of entry via drainage.

4 Honeybees, bumble bees and solitary bees

4.1 Risk assessment for bees

4.1.1 Background

The risk assessment for bees has to be conducted according to the "EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)" (EFSA Journal 2013;11(7):3295).

Up to now there is no agreement to the implementation of the Guidance Document. As recommended in the EFSA technical report (PRAS 133): "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (EFSA supporting publication 2015:EN-924), the Tier 1 of the risk assessment should be conducted according to the current EFSA Bee Guidance Document, in case the new data requirements according to Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 apply (which is for dossiers submitted after 1 January 2014).

For bees several different possibilities for exposure to a plant protection product exist. The following scenarios are assessed:

i. Exposure via contact (spray deposits, dust drift)
ii. Consumption of pollen and nectar (treated crops, weeds in the field, plants in field margin, adjacent crops; succeeding crops/permanent crop: see Appendix A below)
iii. Risk from metabolites present in pollen and nectar to be assessed in case peer-reviewed data are available

4.1.2 Choice of ecotoxicological endpoint

In standard laboratory tests the following endpoints are in general derived for the active substance and established in the List of Endpoints (LoEP) of an active substance. The values from the LoEP provide the basis for the risk assessment:

i. Acute oral and contact toxicity to bees: LD_{50} [µg a.s./bee]
ii. Chronic oral toxicity to bees: LDD_{50} [µg a.s./bee/day]
iii. Toxicity to larvae: NOED or ED_{10} [µg a.s./larvae/development period]

For the approval of plant protection products, bee toxicity has to be addressed.

For solo formulations (containing one a.s.) acute toxicity studies have to be provided. In case product studies indicate higher toxicity compared to the a.s., chronic studies may be required.

In case the product contains more than one active substance or a safener acute and chronic toxicity have to be addressed.

4.1.3 National risk assessment

Currently there is no harmonisation as regards the risk assessment for bees. National decisions and requirements are summarised in the following:

i. EFSA (2013) should be used for products where the new data requirements apply.
ii. In case bumble bee or solitary bee data are available, a respective risk assessment according to EFSA (2013) should also be conducted. At the time being, such data are not strictly required (following the technical report (PRAS 133) recommendation).

iii. Studies according to OECD GD No. 239 (2021, repeated exposure, including pupation) should be submitted to address the data requirement for honeybee larvae.
iv. Studies with a comparable product may be considered for the assessment in a case-by-case decision.
v. For products containing more than one active substance the submission of toxicity data with the respective active substances or solo-products is not sufficient to address the risk to honeybees.
vi. In case individual required toxicity studies are missing, but an acceptable risk is indicated by the toxicity studies provided, labelling of the product will be considered.
vii. For higher-tier risk assessment an assessment based on the data available and expert judgement is performed, taking into account also elements from EFSA (2013) (following the technical report (PRAS 133) recommendation).

4.2 Risk mitigation measures

In respect to reducing the risk of exposure to bees labelling of the product with SPe 8 is possible, e.g.:

"Dangerous to bees. To protect bees and other pollinating insects

i. do not apply to crop plants when in flower or when flowering weeds are present.
ii. Do not use where bees are actively foraging.
iii. Do not apply when flowering weeds are present.
iv. For the protection of bees and other pollinators wind drift to adjacent non-cultivated land must be avoided, and the plant protection product must be applied using drift-reduction techniques (nozzles: at least XX % drift reduction) within 20 meters from adjacent non-cultivated land (with the exception of boundary strips, hedges and wooded grooves less than 3 meters wide as well as streets, roads and squares). (Decree GZ. 69.102/13-VI/B9a/01 of the BMLFUW from 7th Nov., 2001 in its currently valid version)"
v. Etc.

„Bienengefährlich. Zum Schutz von Bienen und anderen bestäubenden Insekten

i. nicht auf blühende Kulturen aufbringen.
ii. Nicht an Stellen anwenden, an denen Bienen aktiv auf Futtersuche sind.
iii. Nicht in Anwesenheit von blühenden Unkräutern anwenden.
iv. Zum Schutz von Bienen und anderen bestäubenden Insekten ist eine Abdrift in angrenzendes Nichtkulturland zu vermeiden und das Pflanzenschutzmittel in einer Breite von mindestens 20 m zu angrenzendem Nichtkulturland (ausgenommen Feldraine, Hecken und Gehölzinseln unter 3 m Breite sowie Straßen, Wege und Plätze) mit abdriftmindernder Technik (mind. XX %, gemäß ...) auszubringen."
v. Etc.

6 Non-target arthropods other than bees

6.1 Risk assessment for non-target arthropods other than bees

6.1.1 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 LR_{50} 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.

6.1.2 Choice of ecotoxicological endpoint

In standard laboratory tests conducted with plant protection products the focus is on the derivation of LR_{50} values, although the data for the derivation of an ER_{50} is available. It was agreed at the Central Zone Harmonisation Meeting in Wageningen (2022) to use the ER_{50} if lower than the LR_{50} for Tier 1 as well, therefore both endpoints are relevant for the Tier 1 assessment. In higher tier studies (e.g. extended laboratory studies, field studies, etc.) lethal effects (LR_{50}) as well as reproduction or other sublethal effects (ER_{50}) are derived by default and are considered for the risk assessment.

6.1.4 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-colonisation 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-colonisation/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. Standard laboratory studies (Tier I) need to provide both LR_{50} and ER_{50} values. The lower endpoint will be used in the risk assessment.
ii. 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.
iii. In case a high in-field risk was identified an aged residue study with at least the most sensitive species has to be submitted to address the risk. In case residue trials are available the refined DT_{50} 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.

6.2 Risk mitigation measures

The following risk mitigation 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.

7 Earthworms and other soil non-target macro organisms

7.1 Risk assessment for earthworms and other soil non-target macro organisms

7.1.1 Background

The risk assessment for earthworms and other soil non-target macro-organisms has to be conducted according to the EC terrestrial guidance document (Terrestrial Guidance Document, SANCO/10329/2002, October 2002).

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 testing on *Folsomia candida* and *Hypoaspis aculeifer* is required, irrespective of the conclusion on the risk assessment for non-target arthropods or the method of application.

Testing on *Folsomia candida* and *Hypoaspis aculeifer* is also required for all relevant soil metabolites, if not analytically verified in the study with the parent.

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.

7.1.2 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.

7.1.3 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.

7.1.4 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), Sheppard *et al*. (1997), de Jong (2006) and EFSA Supporting publication (2019).

7.1.5 National risk assessment

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:

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

7.2 Risk mitigation

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

9 Soil microbial activity

9.1 Risk assessment for soil micro organisms

9.1.1 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}).

9.1.2 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.

9.1.3 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 in the intermediate time intervals of the study.

If the effect in the last intermediate time interval (14-28 days) is greater than ±25%, even if not statistically significant, the study has to be extended.

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

9.1.4 National risk assessment

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

9.2 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.

10 Non-target terrestrial plants

10.1 Risk assessment for non-target terrestrial plants

10.1.1 Background

The risk assessment for non-target terrestrial plants has to be conducted according to the EC terrestrial guidance document (SANCO/10329/2002 rev 2 final) and under consideration of the relevant part "6. Non-target terrestrial plants" in EFSA Supporting publication 2019:EN-1673.

The exposure assessment of terrestrial plants uses as surrogate the drift models produced by the BBA for the exposure assessment of aquatic organisms (Ganzelmeier *et al*. 1995, later updated by Rautmann *et al*. 2001).

A tiered approach is suggested starting with available data and proceeding to further steps if required. Data are not required, where exposure is negligible, e.g. in the case of rodenticides, substances used for wound protection or seed treatment, or in the case of substances used in stored products or in glasshouses.

Tier 1: Initial decision on the likelihood for terrestrial plant effects
This assessment step is based on initial screening data. There should be at least 6 species from different taxa tested. As a general rule, the risk should be considered acceptable if there are no data indicating more than 50 % phytotoxic effect at the maximum application rate. If the results show more than 50 % effect for one species or clear indications of effects on more than one species, data requirements and assessment move to the next tier.

Tier 2: Quantitative risk assessment
This tier is a quantitative risk assessment following a TER approach. Dose-response tests on 6 – 10 plant species of different taxa should be provided, where it should be avoided to include a high number of insensitive species. Effect data are represented by ER_{50} values from the studies. There are two options, a deterministic and a probabilistic approach, the choice should be made with regard to the available data set.

i. Deterministic approach: If the TER based on the most sensitive non-target terrestrial plant species is greater than the trigger value of 5, effects on non-target plants are considered acceptable. This trigger of 5 presupposes that at least 6 species have been tested.
ii. Probabilistic approach: Probabilistic methods that make use of the species sensitivity distribution (SSD) can be used in this assessment step if data from 6-10 plant species are available. If the ER_{50} for less than 5 % (often referred to as HR_5) of the non-target terrestrial plant species is below the highest predicted exposure level (PER), the risk for terrestrial plants is assumed to be acceptable (i.e., $HR_5/PER > 1$).

10.1.2 Choice of ecotoxicological endpoint

For the choice of endpoints aside of the standard endpoints listed in the non-target terrestrial plant test guidelines also visual phytotoxicity must be considered if present in the available studies (see "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" EFSA Supporting publication 2019:EN-1673, page 26).

For products (with one or more a.s.) the selection of tested species in the provided effect studies should include the non-target terrestrial plant species which were most sensitive to the individual a.s. according to the active substance evaluation.

10.1.3 Higher tier risk assessment

The higher tier risk assessment (Tier 3) is based on (semi-)field studies. A higher tier risk characterisation and therefore, a case-by-case analysis is required at this stage.

10.1.4 National risk assessment

To consider multiple application patterns in the non-target terrestrial plant risk assessment, a default MAF according to the Guidance Document on Work Sharing in the Norther Zone in the Authorisation of Plant Protection Products (2021) must be applied.

10.2 Risk mitigation

In respect to the risk assessment the following risk mitigation measures may be applied in Austria:

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 in-field unsprayed buffer zone.

11 Assessment of negative effects on biodiversity

As laid out in Commission Regulation (EC) No 1107/2009 (Chapter II, Section 1, Subsection 1, Article 4, (3) e (ii) & (iii)) plant protection products shall have no unacceptable effects on the environment. In order to address this demand, potential impacts on (i) non-target organisms and (ii) biodiversity and the ecosystem shall be assessed with appropriate scientific methods that are accepted by EFSA. For the latter (i.e. impacts on biodiversity and the ecosystem), an evaluation of indirect effects, resulting from trophic interactions within the food web of organisms, need to be included in the risk assessment. An evaluation of these complex ecological interactions is also required according to the data requirements for active substances defined in Commission Regulation (EU) No 283/2013 (Part A, Section 8, Introduction 5), where it is stated that „the potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered." Further, in the Uniform Principles for evaluation and authorisation of plant protection products (Commission Regulation (EU) No 546/2011, Part I, C. Decision-Making, 1. General principles 1.5) it is acknowledged that the evaluation of effects has to be based on data derived by a limited amount of representative species, yet it is stated that "Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.". However, currently no EU-harmonised approach and no method officially accepted by EFSA for the assessment of indirect effects on biodiversity (including trophic interactions) is available. Hence, for the time being the potential impact on biodiversity cannot be considered as mandatory part of the ecotoxicological risk assessment. As a consequence, based on the present risk assessment, negative effects on biodiversity (including trophic interactions) cannot be ruled out.

12 Biopesticides

12.1 Macro-organisms

For macro-organisms (also called "beneficials") no specific EU data requirements or risk assessment procedure are defined. On national level, however, data are required for the assessment of the potential risk of releases of exotic macro-organisms in the field and in protected crops. Data should address the following:

i. the potential of an exotic species to establish,
ii. the potential of dispersal,
iii. the host range/specificity and direct effects on non-target organisms,
iv. the indirect effects of released species on non-target-organisms and
v. whether the exotic macro-organism provides better pest control than indigenous species.

For species native in Austria a proof of natural occurrence is sufficient, and no risk assessment is required.

12.2 Pheromones and semiochemicals

For pheromones and semiochemicals no specific data requirements are defined, generally the data requirements for chemicals apply – under consideration of appropriate waiver options. Waiving of studies or data should be discussed in pre-submission meetings.

Guidance documents:

i. Guidance document on semiochemical active substances and plant protection products, Series on Pesticides, No. 93, 10-Jan-2018 (ENV/JM/MONO(2017)33).
ii. Guidance document on semiochemical active substances and plant protection products, SANTE/12815/2014 rev. 6, July 2023. **[currently a draft version]**

The national risk assessment follows the approaches on EU level.

12.3 Micro-organisms

For micro-organisms specific (revised) data requirements are available, EU Reg. 283/2013 (2022/1439) and EU Reg. 284/2013 (2022/1440). Further, there are specific uniform principles EU Reg. 546/2011 (2022/1441).

Guidance documents:

i. Micro-organism data requirements:
   - Explanatory notes for the authorisation of plant protection products containing an active substance that is a micro-organism according to Reg. (EC) No 1107/2009 **[currently a draft version]**
ii. Risk assessment:
   - Working Document to the Environmental Safety Evaluation of Microbial Biocontrol Agents, SANCO/12117/2012 –rev. 0, September 2012
   - OECD Guidance to the environmental safety evaluation of microbial biocontrol agents, Series on Pesticides, No. 67, 17-Feb-2012 (ENV/JM/MONO(2012)1).
   - PRAPeR M2 (16-18 February 2009)
   - Pesticides peer review meeting on general recurring issues in fate and behaviour and ecotoxicology related to the environmental risk assessment of micro-organisms (23-25 Oct 2023) **[to be published]**

iii. Secondary metabolites:
- Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances in accordance with Article 77 of Regulation (EC) No 1107/2009; SANCO/2020/12258

iv. Baculovirus GD:
- **[New OECD GD being currently finalised]**
- Guidance Document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC; SANCO/0253/2008 rev. 2

v. Bacteriophages:
- Guidance Document for the Regulatory Framework for the Microorganism Group: Bacteriophages; Series on Pesticides No. 108; ENV/CBC/MONO(2022)40

The national risk assessment follows the approaches on EU level.

12.4 Botanicals and plant extracts

For botanicals and plant extracts no specific data requirements are defined, generally the data requirements for chemicals apply – under consideration of appropriate waiver options. Waiving of studies or data should be discussed in pre-submission meetings.

Guidance documents:

i. Guidance document on botanical active substances used in plant protection products, Series on Pesticides, No. 90, 05-Apr-2017 (ENV/JM/MONO(2017)6)
ii. SANCO/11470/2012– rev. 8, 20 March 2014 (which is essentially equivalent to ENV/JM/MONO(2017)6)

The national risk assessment follows the approaches on EU level.

12.5 Other types of biopesticides (e.g. RNA, peptides, etc.)

For other types of biopesticides – currently – no specific data requirements are defined, generally the data requirements for chemicals apply – under consideration of appropriate waiver options. Waiving of studies or data and risk assessment strategies should be discussed in pre-submission meetings.

Guidance documents:

i. RNA:
- Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied ds-RNA-Based Pesticides, Series on Pesticides No. 104, 25 September 2020 (ENV/JM/MONO(2020)26).

The national risk assessment follows the approaches on EU level.

14 Safeners

14.1 Risk assessment of formulations including a safener

14.1.1 Background

According to the currently valid 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, similar rules to active substances should be applied for the authorisation of safeners and synergists.

For plant protection products which include safeners, the assessment should be addressed in the national addendum until data requirements on an EU level are set (in accordance with agreement 95 of the Central Zone Steering Committee from 2014).

14.1.2 National Risk Assessment

For birds and mammals, if endpoints for the safener are available, a risk assessment based on combitox calculations shall be provided in addition to the risk assessment for the active substance.

For aquatic organisms, if endpoints for the safener are available, a risk assessment based on MixTox calculations shall be provided in addition to the risk assessment with endpoints for the plant protection product and the active substances.

For all other non-target organisms, a combined toxicity does not have to be addressed, as long as formulation endpoints including the safener are available.

Appendix A

The relevance of the succeeding crop scenario is assessed according to the EFSA bee GD (2023) Section 4.3.4 as follows:

A necessary condition for the applicability of the screening level is that all the toxicity endpoints (i.e. all the acute LD_{50} values, the LDD_{50} and the larval ED_{50}) must be ≥ 0.1 µg/bee, ≥ 0.1 µg/bee/day and ≥ 0.1 µg/larva/developmental period.

1) Screening level for the relevance of the succeeding crop exposure scenario based on different combinations of soil persistence (soil $DegT_{50}$) and adsorption properties (K_{oc}) of a substance and application rates (expressed as total annual application) to permanent crops. The screening level is applicable only when all the toxicity endpoints (i.e. all the acute LD_{50} values, the LDD_{50} and the larval ED_{50}) are ≥ 0.1 µg/bee. When the properties of a substance meet one of the combinations, an exposure assessment of the succeeding crop scenario is not needed.

Application rate ≤ 100 g/ha	**Application rate ≤ 500 g/ha**	**Application rate ≤ 1 kg/ha**	**Application rate ≤ 5 kg/ha**	**Application rate ≤ 10 kg/ha**
Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g
Soil DT_{50} ≤ 10 d K_{oc} ≥ 500 mL/g	Soil DT_{50} ≤ 5 d K_{oc} ≥ 500 mL/g	Soil DT_{50} ≤ 5 d K_{oc} ≥ 500 mL/g	-	-
Soil DT_{50} ≤ 30 d K_{oc} ≥ 2000 mL/g	Soil DT_{50} ≤ 10 d K_{oc} ≥ 2000 mL/g	Soil DT_{50} ≤ 10 d K_{oc} ≥ 5000 mL/g	-	-
Soil DT_{50} ≤ 60 d K_{oc} ≥ 5000 mL/g	-	-	-	-

2) Screening level for the relevance of the succeeding crop exposure scenario based on different combinations of soil persistence (soil $DegT_{50}$) and adsorption properties (K_{oc}) of a substance and application rates (expressed as total annual application) to annual 'double' crops. The screening level is applicable only when all the toxicity endpoints (i.e. all the acute LD_{50} values, the LDD_{50} and the larval ED_{50}) are ≥ 0.1 µg/bee. When the properties of a substance meet one of the combinations, an exposure assessment of the succeeding crop scenario is not needed.

Application rate ≤ 100 g/ha	**Application rate ≤ 500 g/ha**	**Application rate ≤ 1 kg/ha**	**Application rate ≤ 5 kg/ha**	**Application rate ≤ 10 kg/ha**
Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 500 mL/g	Soil DT_{50} ≤ 2 d K_{oc} ≥ 100 mL/g	Soil DT_{50} ≤ 2 d K_{oc} ≥ 100 mL/g
Soil DT_{50} ≤ 5 d K_{oc} ≥ 500 mL/g	Soil DT_{50} ≤ 5 d K_{oc} ≥ 500 mL/g	Soil DT_{50} ≤ 5 d K_{oc} ≥ 5000 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 2000 mL/g	Soil DT_{50} ≤ 3 d K_{oc} ≥ 5000 mL/g
Soil DT_{50} ≤ 10 d K_{oc} ≥ 2000 mL/g	-	-	-	-
Soil DT_{50} ≤ 30 d K_{oc} ≥ 5000 mL/g	-	-	-	-

In case the exposure scenario is relevant, an assessment according to EFSA bee GD (2013) is required. Also in case at least one toxicity value is < 0.1 µg/bee, an assessment according to EFSA bee GD (2013) has to be performed.

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Abbreviations

AF	Assessment factor
AIR	Annex I Renewal
a.s.	Active substance
DDD	Daily dietary dose
DGD	Daily granule dose
DGritD	Daily grit dose
dRR	Draft registration report
DT_{50}	Degradation time
EC_x	Half maximal (X%) effect concentration related to biomass growth (b), growth rate (r) or yield (y)
ED_{10}	Effect dose 10 %
EFSA	European Food Safety Authority
ERO	Ecological recovery option
ETO	Ecological threshold option
FOCUS	FOrum for Co-ordination of pesticide fate models and their USe
f_{twa}	Time weighted average factor
GD	Guidance document
GAP	Good agricultural practice
HQ	Hazard quotient
HR_5	Hazardous rate, 5^{th} percentile
K_{oc}	Organic carbon absorption coefficient
LC_X	Lethal concentration (X%)
LD_{50}	Lethal dose 50 %
LDD_{50}	Lethal dietary dose 50 %
LoEP	List of endpoints
LR_x	Lethal rate (X%)
MAF	Multiple application factor
NOEC	No observed effect concentration
NOED	no observed effect dose
PD	Composition of diet obtained from treated
PEC_{gw}	Predicted environmental concentration in groundwater
PEC_{soil}	Predicted environmental concentration in soil
PEC_{sed}	Predicted environmental concentration in sediments
PEC_{sw}	Predicted environmental concentration in surface water
$PEC_{sw, twa}$	Time weighted average of the predicted environmental concentration in surface waters
PER	Predicted environmental rate
P_{ow}	Octanol-water partition coefficient
PPP	Plant protection products
PT	Proportion of animals daily diet obtained in habitat treated with pesticide
RAC	Regulatory acceptable concentration
SSD	Species sensitivity distribution
TER	Toxicity exposure ratio
twa	Time weighted average