Austrian
Federal Office for
Food Safety
BAES

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

Information for notifier/applicant and other interested parties

Document version 05

08/2026

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Overview

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 hereinafter. 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 , setting out the data requirements for active substances and (EU) No 284/2013 , setting out the data requirements for plant protection products and (EU) No 546/2011 regarding uniform principles for evaluation and authorisation of plant protection products in accordance with Regulation (EC) No 1107/2009 .

In addition to the above mentioned regulations, the following publications and manuals are followed at zonal and national level, except otherwise stated [1].

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)

[1] The information on the Guidance Documents, publications and manuals used for the risk assessment can be found in the national assessment report.

1 Birds and Mammals

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)

1.1 Risk assessment for birds and mammals

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), for dossiers submitted before October 1, 2025. The risk assessment for birds and mammals of dossiers submitted after October 1, 2025, has to be conducted according to updated "EFSA Guidance for Risk Assessment for Birds and Mammals" (EFSA Journal 2023;21 (2):7790 December 2022).

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 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 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.

1.1.1 Choice of ecotoxicological endpoint

The assessment of the impact caused by acute exposure is based on the lowest of the LD50 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), LD10 and LD20 shall be reported as well. A refinement of EU agreed endpoints is not acceptable. Accordingly, no BMD will be used for the active substance, until it has been derived at EU level (in particular as part of the approval or renewal of approval of the active substance).

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 LD50) are relevant for the latter. This short-term endpoint is only used for the risk assessment in case it is lower than the acute LD50 and not an unbound value.

Product studies for birds are only required in the case that 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.

1.1.2 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 (SV) are provided in the respective EFSA Guidance for Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438 and EFSA Journal 2023; 21(2):7790).

The respective LD50, LD10 or NOEC is set in 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).

If a TWA may be used for the long-term assessment, it is to be assessed by one MS on behalf of the other MSs of the EU (PAI/iZSC meeting September 2025). To set the ftwa, the procedure described in the Guidance document on the evaluation of new data on an active substance submitted post (renewal of) approval (SANCO/10328/2004-rev 10, 2004) is to be followed.

1.1.3 Secondary poisoning

According to the EFSA Guidance for Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438) a log Kow ≥ 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.

iii. 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,21dtwa, for persistent substances the PECsoil,21dtwa + the plateau PECsoil 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.

iv. For the risk assessment for fish-eating birds and mammals in general the RACaqua is used. For detailed information regarding the RAC, please refer to document

"Risk assessment for Aquatic organisms, point 2.4 Regulatory acceptable concentration".

According to the EFSA Journal 2023; 21(2):7790 the risk through secondary poisoning is assessed for earthworm-eating, fish-eating and additionally for benthos-eating birds and mammals.

i. Risk assessment for earthworm-eating birds and mammals: Even though the pore water approach is considered the most scientifically appropriate option, it is recommended to use the dry soil approach until modelling tools for pore water concentrations are developed. For the dry soil approach the 7-d TWA PECsoil;tot should be chosen.
ii. For the risk assessment for fish-eating birds and mammals the 21-d TWA PECsw and the BCFfish from the aquatic section should be chosen. The default BMF values are listed in EFSA Journal 2023; 21(2):7790.
iii. The risk assessment for benthic invertebrate-eating birds and mammals is required as soon as modelling tools for the concentrations in pore water are implemented. Lumbriculus variegatus is used as a model species and the risk assessment is based on the pore water approach.

1.1.4 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.

Regarding the puddle scenario: In general, the puddle scenario is required for all spray applications.

Considering 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.

Regarding the leaf scenario: This should be considered for birds in all leafy vegetables potentially forming water reservoirs. For details, please refer to the respective guidance document. This exposure route is not considered relevant for mammals.

The MAFm value used in the drinking water risk assessment should be calculated considering the soil DT50 value. The geomean DT50 soil (used in the environmental fate section for the calculation of the PECgw and PECsw) should be used. The DT50 soil for risk assessments as part of submissions after October 1, 2025, is described in EFSA Journal 2023; 21(2):7790.

1.1.5 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."

Applications submitted after June 15, 2016, have to address the acute and long-term combined toxicity for birds and mammals.

1.1.6 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 and the MAF should be based on the intended application interval with the time moving window approach.
If the risk assessment goes into higher tier (i.e. if any default parameters are changed, e.g. PD or interception etc.) then also for the standard DT_{50} of 10 days the moving time window approach must be used according to the actual application pattern.

ii. Until the EFSA Journal 2023, 21(2):7790 is in force, the RUD values may be refined using the arithmetic mean values listed in EFSA Journal 2023, 21(2):7790. For fruits the geometric mean values listed in EFSA Journal 2023; 21(2):7790 may be used. Please note, that if the risk assessment is based on RUD values of EFSA GD (2023), these values have to be used for all scenarios, acute and long-term for birds and mammals. (CZHW Brussels, 2025).

iii. Similarly, until the EFSA Journal 2023, 21(2):7790 is in force, the interception values listed therein may be used for those growth stages identified in EFSA Journal 2009, 7(12):1438. (CZHW Brussels, 2025).

1.1.7 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 (see EFSA Guidance for Risk Assessment for Birds and Mammals 2009, 2023).

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 to 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).

1.1.8 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.

1.1.9 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

The following risk mitigations measures may be applied:

i. Reduction of the application rate
ii. Reduction/adaption of application window
iii. Risk phrases (e.g. SPe 5, SPe 6, etc.)

2 Aquatic organisms

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)

2.1 Risk assessment for aquatic organisms

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 (AF) 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.

2.1.1 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.

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).

2.1.2 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 the 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).

For the choice of endpoints aside of the standard endpoints listed in the non-target aquatic macrophyte test guidelines also visual phytotoxicity shall be considered (as decided during the Central Zone Harmonisation Meeting, Brussels 2025).

2.1.3 Regulatory acceptable concentration (RAC)

The regulatory acceptable concentration is derived from the approved ecotoxicological endpoint and directly compared with the relevant predicted environmental concentration (PEC). For further information, please refer to eFate National Exposure Assessment Requirements.

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.

2.1.4 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 respective dRR template which is recommended to be used for the mixture toxicity assessment can 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.

2.1.5 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).

2.1.6 National risk assessment

The national risk assessment is largely in line with the current EU approach. 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 PECsw values has to be provided on national level. 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.
vi. Restrictions regarding the number of applications per crop and year. This mitigation measure might be required as a result from the ground water risk assessment (2.1.9, ii).

3 Honeybees, bumble bees and solitary bees

The following publications and manuals are followed at zonal and national level, except otherwise stated [2].

[2] The information on the Guidance Documents, publications and manuals used for the risk assessment can be found in the national assessment report.

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)

3.1 Risk assessment for bees

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).

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 (2013).

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 **Error! Reference source not found.** below)
iii. Risk from metabolites present in pollen and nectar to be assessed in case peer-reviewed data are available

3.1.1 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 the toxicity of the formulation can be reliably predicted from the active substance chronic toxicity studies (adults and larvae) with the solo formulation are not strictly required. Decision should be made based on the available acute toxicity studies conducted with the active substance and the formulation.

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

3.1.2 National risk assessment

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) have to 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. Until entry into force of EFSA guidance document (2023), the following transitional rule applies for the two scenarios “drinking water” and “uptake of pollen and nectar in succeeding crops” on the basis of EFSA (2023):
- a drinking water risk assessment (guttation water, water in puddles and surface water) does not need to be performed
- before performing an assessment of the exposure scenario "succeeding crop", the relevance of the exposure scenario for the applied crop shall be verified. The guidance in the EFSA guidance document of 2023 (section 4.3.4) shall be followed, i.e. based on the properties (DT_{50} in soil, K_{oc}) and toxicity of the active substance as well as the application rate, the relevance of the exposure scenario

shall be decided. If the exposure scenario is considered relevant, an assessment shall be performed according to EFSA (2013).

viii. 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 recommendation of EFSA supporting publication 2015:EN-924).

3.1.3 Risk mitigation measures for bees

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)."
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.

4 Non-target arthropods other than bees

The following publications and manuals are followed at zonal and national level, except otherwise stated [3].

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)

4.1 Risk assessment for non-target arthropods other than bees

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 "Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC" (SANCO/10329/2002 rev 2 final).

For non-target arthropods the hazard evaluation at Tier 1 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} or ER_{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 (PER) 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.

[3] The information on the Guidance Documents, publications and manuals used for the risk assessment can be found in the national assessment report.

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 5 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 of 10 might not be fully appropriate in the light of current knowledge. This decision was backed by the CZSC 12.04.2024, which confirmed a VDF of 5.

In higher tier tests, this vegetation distribution factor is depending on the mode of the testing (a factor of 5 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.

4.1.1 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.

4.1.2 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.

4.1.3 National risk assessment

The national risk assessment is according to the current EU wide harmonised approach. The following points should be considered for the national assessment.

i. Standard laboratory studies (Tier 1) 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.

4.2 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. In June 2024, EFSA received two mandates from the European Commission (EC): (1) to review the Guidance Document on Terrestrial Ecotoxicology and (2) to develop guidance for assessing potential indirect effects on biodiversity through trophic interactions under agro-environmental conditions. Both mandates were issued pursuant to Article 29 of Regulation (EC) No 178/2002, in conjunction with Regulation (EC) No 1107/2009.

5 Earthworms and other soil non-target macro organisms

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)

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

The risk assessment for earthworms and other soil non-target macro-organisms has to be conducted according to the "Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC" (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.

5.1.1 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.

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.

5.1.2 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 OECD 222 test guideline (2016), body weight changes in adult earthworms must be reported in the study report. Significant changes in body weight could impact reproduction and, consequently, have population-level relevance. It was agreed at the Central Zone Harmonisation Meeting in Brussels (2025) to consider body weight change as a relevant endpoint, which should be used in the risk assessment. It should be reported in the study summary and included in the LoEP. 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.

5.1.3 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).

5.1.4 National risk assessment

The national risk assessment is completely in line with the current EU approach. The following point should be considered for the national assessment.

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

5.2 Risk mitigation

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

In 2017 a Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms (EFSA Journal 2017;15(2):4690) was published. In June 2024, EFSA received two mandates from the European Commission (EC): (1) to review the Guidance Document on Terrestrial Ecotoxicology and (2) to develop guidance for assessing potential indirect effects on biodiversity through trophic interactions under agro-environmental conditions. Both mandates were issued pursuant to Article 29 of Regulation (EC) No 178/2002, in conjunction with Regulation (EC) No 1107/2009.

6 Soil microbial activity

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)

6.1 Risk assessment for soil micro organisms

The risk assessment for soil micro-organisms has to be conducted according to the "Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC" (SANCO/10329/2002 rev 2 final).

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

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

6.1.1 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.

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.

6.1.2 Choice of ecotoxicological endpoint

Endpoints for the active substance and their metabolites are listed in the List of Endpoints (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 (section by section) 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}).

6.1.3 National risk assessment

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

6.2 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.

In 2017 a Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms (EFSA Journal 2017;15(2):4690) was published. In June 2024, EFSA received two mandates from the European Commission (EC): (1) to review the Guidance Document on Terrestrial Ecotoxicology and (2) to develop guidance for assessing potential indirect effects on biodiversity through trophic interactions under agro-

environmental conditions. Both mandates were issued pursuant to Article 29 of Regulation (EC) No 178/2002, in conjunction with Regulation (EC) No 1107/2009.

7 Non-target terrestrial plants

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)

7.1 Risk assessment for non-target terrestrial plants

The risk assessment for non-target terrestrial plants has to be conducted according to the "Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC" (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. Both approaches should be calculated provided that the available data set is sufficient. The final choice should be made with regard to the reliability of the results.

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., $HR_5/PER > 1$).

7.1.1 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 shall be considered (see "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology" EFSA Supporting publication 2019:EN-1673, page 26). If the data for visual phytotoxicity is inconclusive, a new study is required.

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.

7.1.2 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.

7.1.3 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 Northern Zone in the Authorisation of Plant Protection Products (2021) must be applied.

i. The default MAF_{leaf} of 2.3:1 should be used for the seedling emergence and vegetative vigour test (i.e. no distinction is made between the MAF_{soil} and the MAF_{leaf}).
ii. No refinement based on interception is accepted.
iii. No refinement based upon DT_{50} (plant materials) is accepted

7.2 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.

In 2014 a Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants (EFSA Journal 2014;12(7):3800) was published. In June 2024, EFSA received two mandates from the European Commission (EC): (1) to review the Guidance Document on Terrestrial Ecotoxicology and (2) to develop guidance for assessing potential indirect effects on biodiversity through trophic interactions

under agro-environmental conditions. Both mandates were issued pursuant to Article 29 of Regulation (EC) No 178/2002, in conjunction with Regulation (EC) No 1107/2009.

8 Assessment of negative effects on biodiversity

As laid out in Regulation (EC) No 1107/2009 plant protection products (PPPs) 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 at Union level. 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, 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 PPPs (Commission Regulation (EU) No 546/2011) 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.*".

Currently, no EU-harmonised approach and no method officially accepted by EFSA for the assessment of indirect effects on biodiversity via trophic interactions is available. The risk assessment of direct effects on non-target species on the lower levels of the food chain such as plants and arthropods, together with information on the range of species potentially affected on higher levels (specific vs broad-spectrum activity) gives already indications on the inherent potential for such effects. A method to consider this information for an initial assessment in a stepwise approach was published by (Solé, 2024).

9 Active substances other than chemicals

The following information refers to the currently valid Regulations and Guidance Documents. The EU Omnibus regulation currently being discussed has not yet been taken into account.

9.1 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.

9.2 Micro-organisms

For micro-organisms specific (revised) data requirements are available, EU Regulation 283/2013 (2022/1439) and EU Regulation 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. (European Commission, 2023)

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. (OECD, 2012)
- PRAPeR M2 (16-18 February 2009)
- Outcome of the Pesticide Peer Review Meeting on general issues for microorganisms (Fate-Ecotoxicology joint session), held 23rd – 25th Oct 2023), (EFSA, 2025)

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**

- Guidance document on Baculoviruses as plant protection products, Series on Pesticides No. 111, (OECD, 2023)
- 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.

dRR templates for plant protection products containing an active substance which is a micro-organism (new templates):

i. dRR templates are accessible via the EU COM website. These tailored dRR templates shall be used by an applicant.

9.3 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, (SANTE/12815/2014 rev. 11), January 2024.

The national risk assessment follows the approaches on EU level.

9.4 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.

9.5 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.

10 Safeners

10.1 Risk assessment of formulations including a safener

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).

10.1.1 National Risk Assessment

For birds and mammals, if endpoints for the safener are available, a risk assessment based on combined toxicity 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 Guidance Document (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	-	-	-	-

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Abbreviations

AF	Assessment factor
AIR	Annex I Renewal
a.s.	Active substance
BMD	Bench Mark Dose
BMF	Biomagnification factor
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
$PEC_{soil,tot}$	Predicted environmental concentration in dry 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

Austrian
Federal Office for
Food Safety
BAES

www.baes.gv.at

Owner, publisher and editor: BAES – Austrian Federal Office for Food Safety,
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