Austrian
Federal Office for
Food Safety
BAES

National exposure assessment for the authorisation of plant protection products (PPP) in Austria: Calculation of predicted environmental concentrations (PEC) in soil, groundwater, surface water, sediment, and air

Information for notifier/applicant and other interested parties

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This document is to be read in conjunction with Regulation (EC) No. 1107/2009 and the Commission Regulations (EU) No. 283/2013 and No. 284/2013 as well as appropriate EU guidance documents with the aim of supporting environmental exposure assessments for active substances and metabolites potentially affecting soil, groundwater, surface water, sediment, and air in Austria. The purpose of this document is to outline Austrian quality standards for the authorisation of plant protection products (PPP). The approaches outlined hereafter include requirements and recommendations for environmental exposure assessments and risk mitigation measures accepted in Austria.

1 Introduction

Following the EU Commission guidance on the evaluation of new active substance data post approval (EC, 2021b) and the Working document of the Central Zone in the Authorization of PPP, Section 8, Environmental Fate & Behaviour (CZSC, 2018), a zonal exposure assessment for a PPP should always be based on

i. EU agreed endpoints as given in the List of Endpoints (LoEP) of the EFSA conclusion or review reports,
ii. EU agreed exposure models and approaches as outlined in FOCUS, EFSA and Commission guidance (also refer to Chapter 7, guidelines and references), and
iii. EU agreed mitigation measures.

New Annex II data for the active substance or metabolites should only be used if safe use conditions cannot be demonstrated using agreed endpoints and agreed mitigation measures. A so-called *baseline* exposure assessment (ignoring new Annex II data) allows national regulators assessing the need for new Annex II data in view of zonal or national risk mitigation measures as outlined in the sections below. AT may ask for such a baseline assessment at national level if considered necessary.

At national level, new Annex II data may be submitted if there is dedicated guidance on how to assess them. This includes laboratory and field degradation (including formation fractions of metabolites), kinetic assessments, soil adsorption, aged sorption, plant uptake refinements with the Brigg's equation, and similar. At national level, AT does not consider new Annex II data if there is no dedicated guidance available on how to assess them. This includes monitoring studies, modelling studies used to set monitoring data into context, and similar[1].

If a PPP is intended to be used in several crops but only a so-called *risk envelope approach* has been provided for these crops, notifiers/applicants must demonstrate that less restrict mitigation measures (e.g., regarding buffer zones) are acceptable for individual crops in

[1] In view of missing dedicated guidance, missing harmonization amongst zonal Member States and insufficient peer-reviews at zonal level, AT does not consider it defensible to evaluate complex higher tier assessments at zonal or national level.

comparison to the risk envelope approach. If this is not demonstrated by the notifier/applicant, risk mitigation measures for a PPP are considered the same for all crops covered by the risk envelope approach.

Notifiers/applicants are highly encouraged to contact the national registration authority in case of any uncertainties regarding the national exposure assessment.

The draft for the national exposure assessment, which must be provided for each national registration, can be downloaded at

https://www.baes.gv.at/zulassung/pflanzenschutzmittel/bewertung.

2 Predicted environmental concentration in soil (PEC_S)

2.1 Background

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 (PEC_S) for the active substance and its metabolites are 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. The DT_{50} used is usually the worst-case degradation/dissipation rate observed in laboratory soil incubation or field dissipation studies submitted by the notifier/applicant. For metabolites the application rate is corrected in relation to the maximum occurrence observed in soil and their molar mass. Currently, plant interception is assumed as a sink quantified according to the crop BBCH stage at application (EFSA, 2014a). In case of multiple applications, the PEC_S is usually based on the last application to account for potential build-up in soil. In case of more persistence compounds (DT_{90} > 1 year) long-term accumulation PEC_S for annual crops are calculated considering annual mixing within the ploughing layer (usually 20 cm). In case of permanent crops or grassland mixing within a tillage layer is usually not accounted for.

2.2 National exposure assessment

The national soil exposure assessment is in line with the present EU approach.

2.3 National requirements

None

2.4 Risk mitigation measures

In respect to the soil exposure assessment the following risk mitigations measures may be applied:

i. Reduction of the application rate.
ii. Restrictions regarding non-permanent use (e.g., 'do not use more than each [second/third] year on the same area') in the case of accumulating substances.

For limited areal applications (e.g., row, band or spot application) the soil exposure assessment must cover the full application rate considering no areal 'dilution'.

2.5 Limitations

The soil exposure assessment at the EU level is under revision; new approaches and a new guidance document have been published by EFSA (2012, 2017). In alignment with the groundwater and surface water exposure assessment, the revised EU soil exposure assessment is based on so-called *realistic worst-case* soil scenarios for each crop and for each Regulatory Zone in the EU. EFSA (2017) also considers crop interception not as a sink and recommends accounting for pesticide wash off from the crop canopy shortly after application.

3 Predicted environmental concentration in the groundwater (PEC_{GW})

3.1 Background

In 2000, the FOCUS groundwater working group defined nine so-called *realistic worst-case* leaching scenarios for the EU (at that time EU-15, FOCUS, 2000). For each scenario the 80th percentile annual average leaching concentration at 1 m soil depth over a continuous use period of 20 years is considered as the evaluation endpoint (PEC_{GW}). To demonstrate safe use conditions, the PEC_{GW} must be below 0.1 µg/L for active substances and relevant metabolites in these scenarios. For non-relevant metabolites PEC_{GW} values up to 10 µg/L are considered acceptable depending on their individual toxicological profile (EC, 2021a). The nine FOCUS groundwater scenarios are widespread all over the EU and are characterized by certain worst-case soil and climatic conditions. It was the intention of the FOCUS working group that each of the nine scenarios covers the overall 90th percentile (i.e., the realistic worst-case) leaching concentration in space and time in the respective FOCUS climate zone. Since then, these nine scenarios were used for the EU groundwater exposure assessment to prove whether there are safe use conditions for a significant crop area in the EU. In principle, one safe FOCUS groundwater scenario is sufficient to demonstrate significant safe use areas at the EU level and to allow for approval at the EU level.

In 2009, the FOCUS groundwater working group further harmonized the FOCUS leaching models (PEARL, PELMO, PRZM and MACRO), revised two of the FOCUS scenarios (Piacenza and Porto) and provided a comprehensive review on the representativeness of each FOCUS scenario for individual Member States (FOCUS, 2009). Despite several shortcomings, EFSA (2013a, 2013b) accepted the outcome of the FOCUS review on the representativeness of each FOCUS groundwater scenario for individual Member States as it was considered the best approach available at that time.

With the adoption of the FOCUS groundwater report (EC, 2014), additional guidance on higher tier groundwater exposure assessments including modelling with refined substance parameters (Tier 2a), modelling with refined scenarios (Tier 2b), combined modelling with refined substance parameters and refined scenarios (Tier 3a), advanced spatial modelling

(Tier 3b), higher tier leaching experiments set into context by modelling (Tier 3c) and other modelling approaches (Tier 3d) was made available at the EU and national level. The highest tier (Tier 4) is represented by groundwater monitoring.

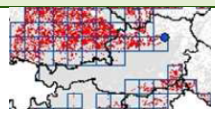
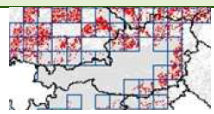
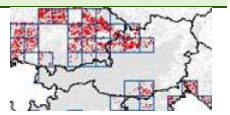
3.2 National exposure assessment

Based on the review of the FOCUS groundwater working group (FOCUS, 2009), the following four FOCUS groundwater scenarios represent pedo-climatic conditions relevant to Austria:

- **Châteaudun**
- **Hamburg**
- **Kremsmünster**
- **Okehampton**

Major pedo-climatic properties of the four FOCUS groundwater scenarios and their national coverage according to FOCUS (2009) are given in Table 1.

Table 1: Major soil and climatic properties of the four FOCUS groundwater scenarios considered representative for Austrian agricultural areas (based on FOCUS, 2009).

FOCUS groundwater scenario	**Châteaudun**	**Hamburg**	**Kremsmünster**	**Okehampton**
Extension of the scenario (as given in FOCUS, 2009) [a]				
Annual average temperature (°C)	11.3	9.0	8.6	10.2
Annual average rainfall (mm)	650	790	900	1040
Annual ref. evapotranspiration (mm)	780	610	670	710
Irrigated	Yes [c]	No	No	No
Annual average groundwater recharge at 1 m soil depth (mm) [b]	270 / 120	260 / 230	330 / 300	440 / 410
Soil classification	Silty clay loam	Sandy loam	Loam / silt loam	Loam
Clay (%), 0 – 30 cm	30	7	14	18
pH (KCl), 0 – 30 cm	7.3	5.7	7.0	5.1
Organic carbon (%), 0 – 30 cm	1.3	1.5	2.1	2.0
Organic carbon (%), 30 – 60 cm	0.8	1.0	0.5	0.6
Organic carbon (%), 60 – 100 cm	0.17	0.05	0.29	0.21
K_{sat} (m/d), 0 – 30 cm / 30 – 60 cm	2.0 / 2.0	2.0 / 2.6	0.2 / 0.2	0.3 / 0.4
Plant available water (mm), 1 m soil depth	160	200	200	200

[a] Blue grid cells: area covered by climate of FOCUS scenario; red areas: area more vulnerable than FOCUS scenario; white areas: area not adequately covered by the FOCUS scenario; grey areas: non-arable land

[b] Example calculation: Maize / Winter cereals, PEARL 4.4.4

[c] Crops irrigated: apples, cabbage, carrots, grass, maize, onions, potatoes, sugar beets, tomatoes, and vines (amount of irrigation is 110 – 400 mm/yr depending on the crop)

If a crop is not covered in a FOCUS scenario, surrogate crops/scenarios as defined in Appendix A should be used.

3.3 National requirements

The national groundwater exposure assessment is in line with the present EU approach including handling of non-relevant metabolites. However, there are some national specifications which deviate from the EU approach:

i. All four national FOCUS groundwater scenarios must demonstrate safe use of the PPP.
ii. The representative modelling tool is FOCUS PEARL with the latest version available.
iii. In case of substance properties depending on soil properties other than organic carbon and clay content (e.g., soil pH dependent sorption) model calculations using reasonable worst-case substance properties with respect to leaching must be provided for each of the four FOCUS groundwater scenarios.
iv. The indicative threshold value of 10 µg/L for non-relevant metabolites (EC, 2021a) should be met, e.g., applying appropriate risk mitigation measures.

Higher Tier assessments are accepted if they are in line with recommendations given in the guidance document on the groundwater exposure assessment (EC, 2014) or other relevant guidance (e.g., guidance on aged sorption, EC, 2021c). This may include refinement of substance properties including aged sorption (Tier 2a) or refinement of the FOCUS scenarios at Tier 2b as stated in EC (2014). Creation of new scenarios (Tier 2b), advanced spatially modelling approaches (Tier 3b), higher tier leaching experiments set into context by modelling (Tier 3c), other higher tier modelling approaches (Tier 3d) or (targeted) groundwater monitoring (Tier 4) set in context with individual Member States' pedoclimatic conditions are only accepted at national level if they have been reviewed and accepted at the level of active substance approval/renewal in the EU.

Data from non-targeted or public groundwater monitoring studies (either conducted in Austria or in other Member States) are currently not accepted. However, adverse data from non-targeted or public groundwater monitoring conducted in Austria (e.g., within the Gewässerzustandüberwachungsverordnung, GZÜV) may be considered on a case-by-case decision.

3.4 Risk mitigation measures

In respect to the groundwater exposure assessment the following risk mitigations measures may be applied at national level:

i. Reduction of the application rate.
ii. Restrictions regarding application timing (e.g., 'do not use before/after [date]').
iii. Restrictions regarding non-permanent use (e.g., 'do not use more than each [second/third] year on the same area').
iv. Restrictions regarding the extent of the soil area treated (e.g., row, band or spot application).
v. Restrictions regarding soil pH.

The appropriateness of the risk mitigation measures i., iii., iv., and v. may be demonstrated by additional model calculations or by applying the following default mitigation measures:

ad i. Reduction of the non-mitigated PEC_{GW} (modelled application rate) by a factor resulting from the intended application rate divided by the modelled application rate.

ad iii. Reduction of the non-mitigated PEC_{GW} (annual use) by a factor of 2 or 3 to account for an intended application every 2nd or 3rd year, respectively (for the rationale behind these factors refer to Appendix B).

ad iv. Reduction of the non-mitigated PEC_{GW} (application to the entire area) with a factor accounting for the actual soil area treated (e.g., if only one third of area is treated, the non-mitigated PEC_{GW} is divided by 3).

ad v. For restricted use on soils with a certain pH range, it must be demonstrated that these soils cover at least 2/3 of the crop growing area in Austria. Substance properties should be related to soil pH measured in $CaCl_2$ or KOH. All four national FOCUS groundwater scenarios must demonstrate safe use of the PPP. For labelling purposes of the PPP, *acidic soils* refer to soils with a $pH_{CaCl2} < 6.5$, *neutral soils* refer to soils with a pH_{CaCl2} from 6.5 – 7.5, and *alkaline soils* refer to soils with a $pH_{CaCl2} > 7.5$. No other pH ranges are foreseen for labelling. E.g., the phrase *no use on neutral and alkaline soils* implies that the PPP must not be used on soils with a $pH_{CaCl2} \geq 6.5$.

3.5 Limitations

The FOCUS scenarios do not adequately account for preferential flow processes in soil (macropores), uncertainties in substance properties (e.g., variability in $DegT_{50}$, K_{OC}) or the impact of soil properties on substance properties (e.g., in case of pH-dependent sorption) (EFSA, 2013a, 2013b).

In their review of the FOCUS groundwater report, EFSA (2013a, 2013b) criticized that most of the higher tier assessments are of high (too high) complexity and guidance given in the report is not necessarily adequate. Groundwater monitoring is considered currently not feasible at the EU level due to insufficient knowledge on groundwater hydrology. EFSA (2023) also highlights that there is currently no specific guidance available on how to design, conduct and evaluate groundwater monitoring studies (Tier 4) for regulatory purposes. At present, a SETAC working group is developing EU wide spatially distributed leaching models (GeoPEARL and GeoPELMO), which may finally (after adoption) be used at Tier 3b and to support in-context setting of groundwater monitoring results at Tier 4.

4 Predicted environmental concentration in the surface water and sediment (PEC_{SW} and PEC_{SED})

4.1 Background

In analogy to the groundwater leaching scenarios, the FOCUS surface water working group has defined 10 realistic worst-case edge-of-field surface water scenarios for the aquatic exposure assessment at the EU level (FOCUS, 2001). In general, exposure of pesticides to edge-of-field 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. For substances with certain properties (high vapour pressure), input via volatilisation and dry deposition is considered as well (FOCUS, 2008). 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 edge-of-field water courses (stream and ditches) with a width of 1 m and a water depth of 0.3 m are accounted for as well as small ponds (30 × 30 × 1 m).

At the EU level risk mitigation with respect to the aquatic exposure assessment may be applied by decreasing the direct input via spray drift (assuming non-spray buffer zones or drift reducing nozzles) and/or by introducing vegetated buffer zones (filter strips) between the treated field and the water course thus reducing input via surface runoff and erosion (FOCUS, 2007).

FOCUS (2001) also includes a comprehensive review on the representativeness of each FOCUS surface water scenarios for individual Member States (EU-15 only at that time).

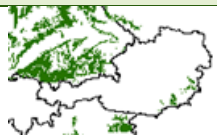
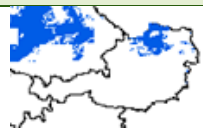
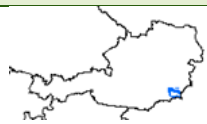
4.2 National assessment

Based on the review of the FOCUS surface water working group (FOCUS, 2001) the following three FOCUS surface water scenarios represent pedo-climatic conditions relevant to Austria:

- **D4 Skousbo**
- **R1 Weiherbach**
- **R3 Bologna**

Major pedo-climatic properties of the three FOCUS surface water scenarios and their national coverage as well as major characteristics of the water bodies according to FOCUS (2001) are given in Table 2 and 3.

Table 2: Major pedo-climatic properties of the three FOCUS surface water scenarios considered representative for Austrian agricultural areas (based on FOCUS, 2001).

FOCUS surface water scenario	**D4 Skousbo**	**R1 Weiherbach**	**R3 Bologna**
Extension of the scenario (as given in FOCUS, 2001)			
Input following soil deposition	Drainage	Runoff	Runoff
Climate	Temperate with moderate precipitation	Temperate with moderate precipitation	Warm temperate with high precipitation
Soil type, drainage conditions	Light loam, slowly permeable at depth and with field drains; slight seasonal water logging by water perched over the slowly permeable substrate	Free draining light silt with small organic matter content	Free draining calcareous heavy loam
Landscape	Gently sloping, undulating land	Gently to moderately sloping, undulating land	Moderately sloping hills with some terraces
Mean annual temperature (°C)	8.2	10.0	13.6

Mean annual precipitation (mm)	710	740	690
Mean annual irrigation (mm)[a]	150 - 180	30 - 130	40 - 300
Mean annual groundwater recharge (mm)	2 / 2[b]	160 / 210[c]	130 / 150[c]
Mean annual runoff (mm)	10 / 10[b]	80 / 40[c]	150 / 90[c]
Mean annual erosion (t/ha)	-	1.6 / 0.8[c]	4.4 / 3.2[c]
Mean annual drain flow (mm)	220 / 190[b]	-	-
Soil texture	Loam	Silt loam	Clay loam
Topsoil organic carbon (%)	1.4	1.2	1.0
Topsoil pH	6.9	7.3	7.9
Drain depth (m)	1.2	-	-
Drain spacing (m)	10	-	-
Slope (%)	0.5 - 2	3	10[d]
Water bodies	Stream, pond	Stream, pond	Stream

[a] Irrigated crops in drainage scenarios: sugar beets, potatoes, vegetables, legumes; irrigated crops in runoff scenarios: sugar beets, potatoes, vegetables, legumes, maize, sunflower

[b] Example calculations: Maize / winter cereals, MACRO 5.2

[c] Example calculations: Maize / winter cereals, PRZM 3.1.1

[d] Terraced to 5 %

Table 3: Major environmental characteristics of the FOCUS surface water bodies 'pond' and 'stream'.

Water body	**Pond**	**Stream**
Average water depth (m)	1	0.3 – 0.5
Dimensions (m)	30 × 30	1 × 100
Average residence time (days)	50	0.1
Area treated (ha)	0.45	1
Catchment area (ha)	0.45	1 + 100 [b]
Area with drainage or runoff with associated pesticide fluxes (ha)	0.45	1 + 20 [a]
Area with pesticide fluxes associated with eroded sediment (ha)	0.45	0.2 [c]

[a] 1 ha treated field plus 20 ha treated fields from upstream catchment

[b] 1 ha treated field plus 100 ha upstream catchment

[c] 20 m corridor to adjacent water body

Calculations based on FOCUS surface water STEP 1, 2 & 3 are considered representative to cover national minimum distances (so-called 'Regelabstände', without applying drift mitigation) between the crop and the top of the bank of 1 m (areal crops) and 3 m (high growing crops), respectively.

If a crop is not covered in a FOCUS scenario, surrogate crops/scenarios as given in Appendix A should be used.

4.3 National requirements

The national surface water exposure assessment is largely in line with the current EU approach. However, there are some national specifications which deviate from the EU approach:

i. In any case, the national FOCUS surface water scenario accounting for drainage (i.e., D4) must demonstrate safe use conditions for the PPP to avoid risk mitigation measures with respect to application in areas vulnerable to drainage.
ii. In the case of the FOCUS runoff scenarios, both scenarios (R1 as well as R3) must indicate safe use conditions for the PPP to avoid risk mitigation measures (i.e., introducing a vegetated buffer zone between the treated field and the surface water body or restrictions with respect to application in areas vulnerable to runoff).

4.4 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 spray drift input by combination of
    a. increasing the distance between the treated field and the top of the bank of the water body to 5, 10, 15, or 20 m; and/or
    b. assuming drift reducing nozzles with an efficiency of 50, 75, and 90 % (the latter reducing drift to 95 % in orchards and vines when combined with hail protection nets) or other drift reducing application techniques (e.g., tunnel sprayer) with an efficiency of 99 %.

iii. Reduction of pesticide input via soil surface runoff and erosion by introducing a vegetated buffer strip of 5, 10, 15, or 20 m (Table 4).

iv. Restrictions regarding the use in areas vulnerable to drainage. This will be the case if safe use conditions for the FOCUS scenario D4 can only be demonstrated ignoring drainage (drainage input switched off). This will lead to the labelling '*No use in areas vulnerable to drainage*'.

v. Restrictions regarding the use in areas vulnerable to runoff. This will be the case if safe use conditions cannot be demonstrated for the FOCUS surface water scenarios accounting for runoff (R1 or R3) following runoff mitigation. This will lead to the labelling *'No use in areas vulnerable to runoff'*.

vi. Restrictions in respect to the extent of area treated (e.g., row, band or spot application)

Reduction of pesticide input into surface water bodies via bullet point iii. must be linked to drift mitigation measures via bullet point ii. This implies that a vegetated buffer strip of, e.g., 10 m also accounts for a non-spray buffer zone of 10 m.

Runoff mitigation via vegetated buffer strips is conducted in line with FOCUS guidance (FOCUS, 2007) using the EU agreed reduction measures for runoff water and eroded sediment at 10 and 20 m amended with national ones at 5 and 15 m (Table 4):

Table 4: EU agreed and national reduction measures (%) for soil surface runoff and erosion attributed to vegetated buffer zones.

Width of vegetated buffer zones (m)	**5[a]**	**10[b]**	**15[c]**	**20[b]**
Reduction in volume of runoff water (%)	40	60	70	80
Reduction in mass of pesticide transported in aqueous phase (%)	40	60	70	80
Reduction in mass of eroded sediment (%)	40	85	90	95
Reduction in mass of pesticide transported in sediment phase (%)	40	85	90	95

[a] Based on EXPOSIT 3.0

[b] FOCUS, 2007

[c] Average of 10 and 20 m

Notifiers/applicants may apply drift and/or runoff mitigation at FOCUS sw STEP-4 using, e.g., the FOCUS SWAN software or other automatization tool.

The modelling software VFSMOD as a runoff mitigation tool is currently not accepted for national aquatic exposure assessments. Implementation of time dependent sorption in the aquatic exposure assessment is accepted only if it was accepted at the EU level.

Risk mitigation in respect to drainage reduction is presently not considered for (as is the same at the EU level).

For row, band, or spot applications (bullet point vi), a modified (mitigated) application rate should be used in the $PEC_{SW/SED}$ calculation (FOCUS surface water STEP 3 & 4). This rate is derived from the non-mitigated application rate, adjusted with a factor reflecting the area treated. However, the drift load to the water body must consistently represent the non-mitigated application rate (drift load is not mitigated in case of row, band or spot applications). For instance, if only one-third of the area is treated, the non-mitigated application rate is divided by a factor of 3, and this reduced (mitigated) application rate is used in the exposure assessment for runoff (PRZM) and drainage (MACRO). However, before running TOXSWA the drift load (mg/m^2) in the TOXSWA input file must be multiplied with a factor of 3 to appropriately consider drift load from non-mitigated applications. It is recommended to modify the drift load in the TOXSWA input file using the FOCUS SWAN software consulting the FOCUS drift calculator in SWASH. In cases involving additional mitigation measures via non-spray buffer zones and vegetated filter strips (FOCUS surface water step 4), it is crucial to adequately account for all mitigation measures applied. For example, in the scenario mentioned above, the given drift load for a non-spray buffer zone of, e.g., 20 m in the TOXSWA input file must also be multiplied by 3. If accounting for volatilisation and dry deposition, it is essential to use non-mitigated application rates for these entries. In the case of FOCUS surface water STEP 1 & 2, the non-mitigated application rate must be applied, while runoff/drainage entry in the STEP 1 & 2 scenario file may be adequately reduced (e.g., by a factor of 3 in the above example).

4.5 Limitations

There are some concerns that potential surface runoff and erosion is underestimated in the FOCUS surface water scenarios due to miscalculation (Klein, 2013). The current approach is also overly sensitive to application timing as only one year is accounted for in the calculations. These issues (and others) will be addressed following the EFSA repair action initiative (EFSA, 2020).

There are also concerns about the proposed maximum runoff mitigation efficiencies of vegetated filter strips given in FOCUS (2007) for substances with a K_{oc} < 2000 mL/g.

Finally, the FOCUS scenarios are primarily intended to account for pesticide exposure at the edge-of-field situation, which may be considered worst case in respect to acute exposure. Long-term (chronic) exposure which may occur in water bodies draining larger watersheds are not accounted for.

5 Predicted environmental concentration in air (PEC_A)

5.1 Background

At the EU level the air exposure assessment is preliminary driven by expert judgment based on the Atkinson calculation (e.g., as implemented in the EPI (Estimation Programs Interface) Suite, US EPA, 2012).

The short-range exposure assessment scheme uses a vapour pressure trigger to identify substances of potential concern. The trigger is 10^{-5} Pa (at 20 °C) if a substance is applied to plant canopies and 10^{-4} Pa (at 20 °C) if the substance is applied to soil surfaces. Substances that exceed these triggers and require drift mitigation to pass the terrestrial or aquatic risk assessment (STEP 4) require deposition following volatilisation, added to deposition from spray drift. Initial quantification is achieved through modelling and, if safety cannot be established through modelling alone, additional experimental data may become necessary.

The FOCUS working group further recommend a trigger DT_{50} in air of 2 days (Atkinson calculation) to identify substances of potential concern for long-range transport (FOCUS, 2008). Substances having a longer DT_{50} require further evaluation to assess their potential impact upon the environment.

5.2 National assessment

The national air exposure assessment is in line with the present EU approach.

6 Other exposure assessments

6.1 Additional exposure assessments for PPP containing more than one active substance

In case of PPP containing more than one active substance additional exposure assessments are required:

i. PEC_S values for the entire product assuming non-degradation (based on total annual application rate considering crop interception, no accumulation assumed).
ii. PEC_{SW} values for the entire product applying the FOCUS drift calculator in FOCUS SWASH (based on a single maximum application if the GAP indicates multiple applications) in streams (upstream catchment area not accounted for).

6.2 Exposure assessment for home and garden use

The area potentially treated with PPP in a typical garden or home use is considered to be at maximum 50 % for lawn, meadows or pathways and 10 % for ornamentals and other crops. Based on these assumptions the following modifications to the exposure assessment for the professional use of PPP are required:

i. PEC_{GW} values calculated on basis of the FOCUS groundwater scenarios may be reduced (diluted) with a factor of 2 (lawn, meadows, pathways) or 10 (ornamentals and crops).
ii. PEC_{SW} calculations are based on FOCUS STEP 1 & 2 only with modified drift values (from JKI):
    a. Crop < 50 cm: 0.42 %
    b. Vine, bush berries and ornamental crops > 50 cm (early/late): 13.52 / 0.72 %
    c. Orchard trees (early/late): 38.09 / 3.53 %

    There is no differentiation into small (< 2 m) and high (> 2 m) orchard trees in the national assessment. Drift values may be modified in the scenario file of FOCUS STEP 1 & 2.
iii. PEC_{SW} values for the product are based on FOCUS sw STEP 1 & 2 (single maximum application if the GAP indicates multiple applications; drift only).

iv. Discharge via drainage/runoff is considered for lawn, meadows, and pathways only, not for ornamentals or spot applications. For lawn, meadows, and pathways the drainage/runoff numbers in the FOCUS STEP 1 & 2 scenario file may be reduced by factor of 2.

Applications for PPPs in private greenhouses situated in homes and gardens are not addressed by the EFSA Guidance Document on protected crops (EFSA, 2014b). This exclusion is based upon the fact that these uses do not align with the requirements stipulated in Regulation (EC) 1107/2009. Instead, uses of PPPs in private greenhouses in homes and gardens should follow the above-mentioned outdoor exposure assessment.

6.3 Exposure assessment for protected crops

In accordance with the EFSA Guidance Document on protected crops (EFSA, 2014b), distinction should be made in the exposure assessment to environmental receptors between the following types of structures:

i. Partially open and/or low structures
ii. Walk-in tunnels
iii. Greenhouses
    a. Soil-less structures
    b. Soil-bound structures
iv. Closed buildings/indoor

In accordance with EU Regulation 1107/2009 (Article 3(27)) a 'greenhouse' is defined as *"*[…] *a walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products (PPPs) into the environment.*" For greenhouse uses, both **soil-bound** and **soil-less** cultivation systems may be considered. The type of system applied must be clearly defined by the notifier/applicant in the GAP table.

For the national exposure assessment, the procedures and methodology described in the Interim working document on the interzonal core assessment of greenhouse uses – environmental fate (izSC, 2023), implemented on 1 September 2024, should be followed. This document provides the harmonised interzonal approach for assessing environmental exposure from PPP use in greenhouses and replaces the earlier national procedures. The interzonal core assessment approach covers all greenhouse types (high- and low-tech; soil-bound and soil-

less) and defines how exposure to soil, groundwater, surface water, sediment, and air should be evaluated.

The national exposure assessment for the different types of structures should be performed as following:

ad i. Partially open and/or low structures: The exposure assessment for all environmental compartments should be performed in line with the present EU approach, based on an equivalent field application rate.

ad ii. Walk-in tunnels: The exposure assessment for soil and groundwater is considered identical to a field application in line with the present EU approach (see chapters 2.2 and 3.2). The exposure assessment for surface water should be based on the FOCUS surface water scenario D4 in line with the present EU approach, assuming an equivalent field application rate (see chapter 4.2). No risk mitigation measures (see chapter 4.4) can be applied. The exposure assessment for air is in line with the present EU approach (see chapter 5.2).

ad iii. Greenhouses:

a. Soil-less structures: Follow the procedures and methodology described in the *Interim working document on the interzonal core assessment of greenhouse uses – environmental fate* (izSC, 2023)
b. Soil-bound structures: Same as bullet point iii.a.

ad iv. Closed buildings/indoor: Exposure assessments for soil, groundwater and surface water are not considered relevant. The exposure assessment for air should be in line with the present EU approach (see chapter 5.2).

7 Guidelines and references

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Appendix A: Surrogate crop/scenario combinations

Table A.1 and A.2 define surrogate crop/scenario combinations which should be used for the groundwater and aquatic exposure assessment if a crop is not represented in a certain scenario.

Note that crop interception must be based on the crop intended (not on the surrogate crop).

Table A.1: Surrogate crop / FOCUS scenario combinations for the groundwater water exposure assessment.

Crop	CH	HA	KR	OK
Apples	✓	✓	✓	✓
Beans (field)	-	✓	✓	✓
Bush berries	CH - vines	HA - vines	KR - vines	-
Cabbage	✓	✓	✓	-
Carrots	✓	✓	✓	-
Grass (= alfalfa)	✓	✓	✓	✓
Hops*	CH - vines	HA - vines	KR - vines	-
Linseed	CH - spring cereals	HA - spring cereals	KR - spring cereals	✓
Maize	✓	✓	✓	✓
Oil seed rape (summer)	CH - spring cereals	HA - spring cereals	KR - spring cereals	✓
Oil seed rape (winter)	✓	✓	✓	✓
Onions	✓	✓	✓	-
Peas (animals)	✓	✓	-	✓
Potatoes	✓	✓	✓	✓
Soybean	CH - maize	HA - maize	KR - maize	OK - maize
Strawberries	CH - spring cereals	✓	✓	OK - spring cereals
Sugar beets	✓	✓	✓	✓
Sunflower	CH - maize	HA - maize	KR - maize	OK - maize
Tomatoes	✓	HA - maize	KR - maize	OK - maize
Spring cereals	✓	✓	✓	✓
Vines	✓	✓	✓	-
Winter cereals	✓	✓	✓	✓

✓ denotes crop adequately covered by FOCUS scenario

- denotes no calculation necessary (minimum of three scenarios available)

* Not a FOCUS gw crop (crop interception in line with vines)

Table A.2: Surrogate crop / FOCUS scenario combinations for the surface water exposure assessment.

Crop	D4	R1	R3
Cereals, spring	✓	R1 - oil seed rape, spring	R3 - legumes
Cereals, winter	✓	✓	✓
Field beans	✓	✓	✓
Grass/Alfalfa	✓	-	✓
Hops	R1 - hops, drift only[a]	✓	-
Legumes	✓	✓	✓
Maize	✓	✓	✓
Oil seed rape, spring	✓	✓	R3 - legumes
Oil seed rape, winter	✓	✓	✓
Pome/stone fruit	✓	✓	✓
Potatoes	✓	✓	✓
Soybean	R3 - soybean, drift only[a]	-	✓
Sugar beets	✓	✓	✓
Sunflowers	D4 - maize	✓	✓
Veg., bulb	✓	✓	✓
Veg., fruiting	D4 - veg., leafy	-	✓
Veg., leafy	✓	✓	✓
Veg., root	D4 - veg., bulb	✓	✓
Vines	R1 - vines, drift only[a]	✓	✓

✓denotes crop adequately covered by FOCUS scenario

- denotes no calculation necessary (only one R scenario considered)

[a] Runoff entries (water and substance flow) have to be switched off during modelling

Appendix B: Groundwater exposure assessment assuming an application each 2nd and 3rd year vs. annual application, applying a default correction factor of 2 and 3

Figure B-1 shows calculated PEC_{GW} values for the FOCUS standard compounds A, D and C (including metabolite Met-C) for the four FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster and Okehampton and for the crops maize, winter cereals, winter oil seed rape and potatoes (1 kg/ha at emergence) either calculated on the basis of an application each 3rd year or assuming annual application following division of the PEC_{GW} by a factor of 3. Analysis of the tested dataset indicates that the two approaches yield comparable results (Figure B-1).

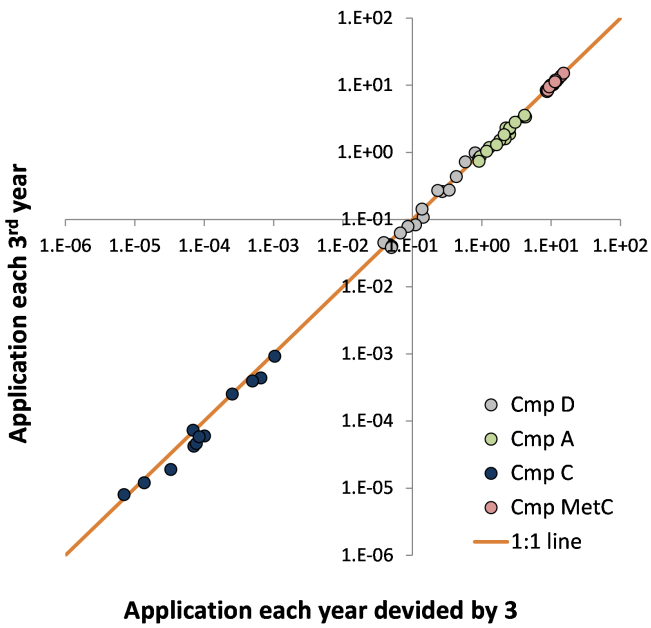

Figure B-1: Calculated PEC_{GW} values (µg L^{-1}) for the FOCUS standard compounds A, D and C (including the metabolite Met-C) for the four FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster and Okehampton and for the crops maize, winter cereals, winter oil seed rape and potatoes (1 kg/ha at emergence) either calculated on the basis of an application each 3rd year or assuming annual application following division of the PEC_{GW} by a factor of 3.

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