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National exposure assessment for the authorization 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 intended to give background information on the environmental exposure assessment for active ingredients and their metabolites currently considered necessary for national approval of plant protection products (PPP) in Austria. The approaches for exposure assessments for soil, groundwater, surface water and air are shortly described hereafter. Recommendations for notifier/applicants including selection of modelling inputs and application of risk mitigation measures for the national exposure assessment are presented.

1 Predicted environmental concentration in soil (*PEC$_S$*)

1.1 Background

At EU level the soil exposure assessment for active substances is presently 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 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 (*DT50*) are accounted for. The *DT50* used is usually the worst-case degradation/dissipation rate found 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. Presently, plant interception is assumed as a sink and applied according to the crop BBCH stage (EFSA, 2014a). In case of multiple applications, the *PEC$_S$* is usually based on the last application in order to account for build-up in soil. In case of more persistence compounds (*DT90* > 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 mixing within a tillage layer is usually not accounted for.

1.2 National exposure assessment

The national soil exposure assessment is largely in line with the present EU assessment approach. However, there are some national specifications which might deviate from the EU approach:

i. In case of multiple application the *PEC$_S$* refers to the *global* maximum *PEC$_S$* occurring during the entire application period (which is not necessarily the final one)
ii. Time weighted average (TWA) *PEC$_S$* values are based on the *global* maximum *PEC$_S$* without considering possible further applications

1.3 National requirements

None

1.4 Risk mitigation measures

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

i. Reduction of the application rate

1.5 Limitations

The soil exposure assessment at the EU level is currently under revision; new approaches and a new guidance document have been published by EFSA (2012, 2017). Similar to 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) now also considers crop interception not as a sink and recommends accounting for pesticide wash off from the crop canopy shortly after application.

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

2.1 Background

In 2001, 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 trigger endpoint (PEC_{GW}). In order to demonstrate safe use conditions the PEC_{GW} has to be below 0.1 µg/L for active substances and relevant metabolites. For non-relevant metabolites PEC_{GW} values up to 10 µg/L are considered acceptable in relation to their toxicological profile (EC, 2003). 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 90th percentile (realistic worst-case) leaching concentration in space and time in the respective climatic zone. Since then these nine scenarios were used for the EU groundwater exposure assessment in order to prove whether there are safe use conditions for a significant crop area in the EU. In principal 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 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 considered to be represented by groundwater monitoring.

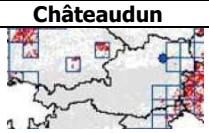
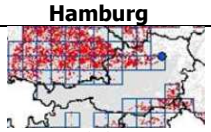
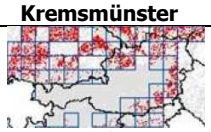
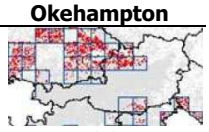
2.2 National exposure assessment

Based on the review of the FOCUS groundwater working group (FOCUS, 2009) the following four FOCUS groundwater scenarios are considered to represent pedo-climatic conditions that can also be found in Austria:

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

Major pedo-climatic properties of the four FOCUS groundwater scenarios and there 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/scenario locations as defined in Appendix A should be used.

2.3 National requirements

The national groundwater exposure assessment is largely 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 of the four national FOCUS groundwater scenarios have to 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 have to be provided for each of the four FOCUS groundwater scenarios
iv. The threshold value of 10 µg/L for non-relevant metabolites (EC, 2003) is considered indicative and should be met 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). This may include refinement of substance properties including aged sorption (Tier 2a), refinement of the FOCUS scenarios (Tier 2b) or creation of new scenarios tailored to a certain crop area applying spatial modelling techniques (Tier 2b/3b). In the case of aged sorption (Tier 2a) the dedicated guidance document should be followed (EC, 2021). Data from non-targeted groundwater monitoring studies (either conducted in Austria or in other Member States) are presently not accepted. However, adverse data from non-targeted public groundwater monitoring conducted in Austria (e.g. within the water framework directive) may be taken into account on a case by case decision. Targeted groundwater monitoring studies, conducted either in Austria or in other Member States, have to be set into context with the FOCUS groundwater scenarios as described in the guidance document (EC, 2014).

2.4 Risk mitigation measures

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

i. Reduction of the application rate
ii. Restrictions in respect to the application timing (e.g. 'do not use before/after [insert date]')
iii. Restrictions in respect to non-permanent use (e.g. 'do not use more than each [second/third] year on the same area')

The appropriateness of these risk mitigation measures may be demonstrated by additional model calculations or by applying the following default mitigation measures to non-mitigated PEC_{GW} values:

i. Reduction of the modelled PEC_{GW} accounting for an intended application rate lower than modelled with a simple reduction factor (*factor* = appl. rate intended / appl. rate modelled)
ii. Reduction of the modelled PEC_{GW} assuming 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)

Risk mitigation in respect to regional soil/climate properties is presently not considered for.

2.5 Limitations

The FOCUS scenarios do not adequately account for preferential flow processes in soil (macropores), uncertainties in substance properties (e.g. variability in *DegT50*, 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.

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

3.1 Background

Similar to the groundwater leaching scenarios, the FOCUS surface water working group has 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. For substances with certain properties (vapour pressure) input via dry deposition may be taken into account 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 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 (30 x 30 x 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 between the treated field and the water course thus reducing input via surface runoff and erosion (FOCUS, 2007).

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

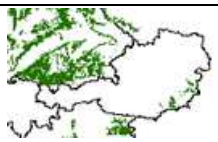
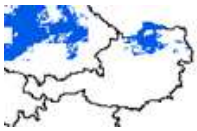
3.2 National assessment

Based on the review of the FOCUS surface water working group (FOCUS, 2001) the following three FOCUS surface water scenarios are considered to represent pedo-climatic conditions which can also be found in 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
Top soil organic carbon (%)	1.4	1.2	1.0
Top soil 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 x 30	1 x 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/scenario locations as given in Appendix A should be used.

3.3 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) has to demonstrate safe use conditions for the PPP in order to avoid risk mitigation measures with respect to application in areas vulnerable to drainage
ii. In case of the FOCUS runoff scenarios, both scenarios (R1 as well as R3) have to indicate safe use conditions for the PPP in order 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)

3.4 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
    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)
iii. Reduction of pesticide input via soil surface runoff and erosion by introducing a vegetated buffer strip of 5, 10, 15 or 20 m
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 *'Do not 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 *'Do not use in areas vulnerable to runoff'*.

Reduction of pesticide input into surface water bodies via bullet point iii) has to be linked to drift mitigation measures via bullet point ii). This means a vegetated buffer strip of e.g. 10 m implies a non-spray buffer zone of 10 m as well.

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 5):

Table 5: 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
[c] FOCUS, 2007
[c] Average of 10 and 20 m

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

The runoff mitigation tool VFSMOD is not accepted.

Risk mitigation in respect to drainage reduction is presently not considered for.

3.5 Limitations

There are some concerns that potential surface runoff and erosion is underestimated in the FOCUS surface water scenarios due to miscalculation (Klein, 2013). This is considered to be adapted in new future via an EFSA repair action (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 L/kg value.

Finally, the FOCUS scenarios are primarily intended to account for pesticide exposure at the edge-of-the-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.

4 Predicted environmental concentration in air (*PEC_A*)

4.1 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 plants and 10^{-4} Pa (at 20 °C) if the substance is applied to soil. Substances that exceed these triggers, and require drift mitigation in order to pass the terrestrial or aquatic risk assessment, need to have deposition following volatilisation quantified and added to deposition from spray drift. Quantification is firstly done by modelling, if safety cannot be demonstrated by this means then further experimental data are required.

The FOCUS working group further recommend a trigger of a *DT50* in air of 2 days (Atkinson calculation) to identify substances of potential concern for long-range transport (FOCUS, 2008). Substances having a longer *DT50* require further evaluation to assess their potential impact upon the environment.

4.2 National assessment

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

5 Other exposure assessments

5.1 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 based on the FOCUS drift calculator in FOCUS SWASH (based on a single application if the GAP indicates multiple applications); stream (upstream catchment area not accounted for)

5.2 Exposure assessment for home and garden use

The area potentially treated with PPP in a typical garden or home use is considered to be 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 the 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 (application by hand only; crop < 50 cm or crop > 50 cm). For ready-to-use products refined drift values published for home & garden use by the Federal Research Centre for Cultivated Plants, Julius Kühn Institute, Germany, may be used if justified.
iii. PEC_{SW} values for the entire product based on FOCUS sw STEP 1 & 2 (based on a single application if the GAP indicates multiple applications; drift only).
iv. Discharge via drainage and runoff is considered for lawn, meadows and pathways only, not for ornamentals or spot applications.

Applications for PPPs in private greenhouses in homes and gardens will not be evaluated following the EFSA Guidance Document on protected crops (EFSA, 2014b), as they will not meet the requirements defined by the Regulation (EC) 1107/2009. The evaluation will be following the above mentioned exposure assessment.

5.3 Exposure assessment for protected crops

According to 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 EU Regulation 1107/2009 a 'greenhouse' (bullet point iii) 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.*" Nevertheless, the type of production system in a greenhouse, i.e. applying either soil-less (impermeable soil) or soil-bound (permeable soil) structures, needs to be defined by the notifier/applicant.

Core assessments should be performed following the agreements reached by the Inter Zonal Steering Committee (izSC).

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

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.
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 chapter 1.2 and 2.2). 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 3.2). No risk mitigation measures (see chapter 3.4) can be applied. The exposure assessment for air is in line with the present EU approach (see chapter 4.2).
iii. Greenhouses:
    a. Soil less structures: Exposure assessments for soil and groundwater are not considered relevant for soil-less structures. The exposure assessment for surface water should be performed as recommended by the so called "Dutch model". The calculation assumes that 0.1 % (aeric mass percent) of the total annual application rate is deposited on surrounding surface water assuming a FOCUS standard water depth of 30 cm. The exposure assessment for air is in line with the present EU approach (see chapter 4.2).
    b. Soil-bound structures: Same as bullet point iii.a) with the exception that an exposure assessment for soil and groundwater is triggered in line with the present EU approach, based on an equivalent field application rate (see chapter 1.2 and 2.2).
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 4.2).

6 General considerations particularly to be taken into account by notifier/applicants

In general, notifier/applicants are highly encouraged to use EU agreed endpoints (as given in the LoEP of the EFSA conclusion or review reports) in context with EU agreed exposure models and approaches as outlined in FOCUS and EFSA guidance (also refer to Chapter 8, guidance and references). New data for the active substance or metabolites (Annex II data) should only be used if safe use conditions cannot be demonstrated on the basis of agreed endpoints (EC, 2012) and after all mitigation measures have been exhausted.

If a PPP is intended to be used in several crops, notifier/applicants have to demonstrate that less restrict mitigation measures (e.g. with respect to buffer zones) may be acceptable for individual crops in comparison to the mitigation measures necessary for the so-called *risk envelope approach*. If this is not demonstrated by the notifier/applicant, risk mitigation measures are considered to be the same for all crops covered by the risk envelope approach.

It is in the responsibility of notifier/applicants to demonstrate that less restrict risk mitigation measures may be acceptable for a certain crop in comparison to the risk assessment for that crop (e.g. within the core assessment) showing save use conditions without less restrict mitigation measures.

Notifier/applicants are highly encouraged to contact the national registration authority in case of any uncertainties regarding the national exposure assessment (e.g. appropriate application timing in model calculations, etc.).

The draft for the national exposure assessment, which has to be provided for each national registration, can be downloaded at https://www.baes.gv.at/zulassung/pflanzenschutzmittel/bewertung/

6 Guidance and references

- EC (2003). Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. SANCO/221/2000, revision 11, 21 October 2021, 18 pp.
- EC (2012). Guidance document on the evaluation of new active substance data post approval, SANCO/10328/2004, revision 9, 21 October 2021, 11 pp.
- EC (2014). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, SANCO/13144/2010, version 3, 10 October 2014, 613 pp.
- EC (2021) Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. SANTE/12586/2020, revision 0, 26 January 2021, 82 pp.
- EFSA (2012). Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations in soil. EFSA Journal 2012; 10(2):2562, 76 pp.
- EFSA (2013a). Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers. EFSA Journal 2013; 11(2):3114, 29 pp.
- EFSA (2013b). Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers. EFSA Journal 2013; 11(6):3291, 25 pp.
- EFSA (2014a). EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014; 12(5):3662, 37 pp.
- EFSA (2014b). EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014; 12(3):3615, 43 pp.
- EFSA (2017). EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2017; 15(10):4982, 115 pp.
- EFSA (2020). Scientific report of EFSA on the 'repair action' of the FOCUS surface water scenarios. EFSA Journal 2020;18(6):6119, 301 pp.
- FOCUS (1997): Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their Use). 77 pp.
- FOCUS (2000): FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000, revision 2, 202 pp.
- FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001, rev. 2, 245 pp.
- FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.
- FOCUS (2007): Landscape and Mitigation Factors in Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005, version 2.0, 169 pp.
- FOCUS (2008): Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006, revision 2, 327 pp.
- FOCUS (2009): Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010, version 1, 604 pp.

- Klein M. (2013) Long term surface water simulations using the FOCUS scenarios. Poster presentation at the York Conference
- US EPA. (2012) Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. United States Environmental Protection Agency, Washington, DC, USA.

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 has to be based on the crop intended (not on the surrogate crop).

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

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

x 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/scenario combinations for the surface water exposure assessment.

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

x 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 factors of 2 and 3

Figure B-1 shows calculated *PEC*$_{GW}$ values 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. Based on the dataset tested there is hardly a difference between the two approaches (Figure B-1).

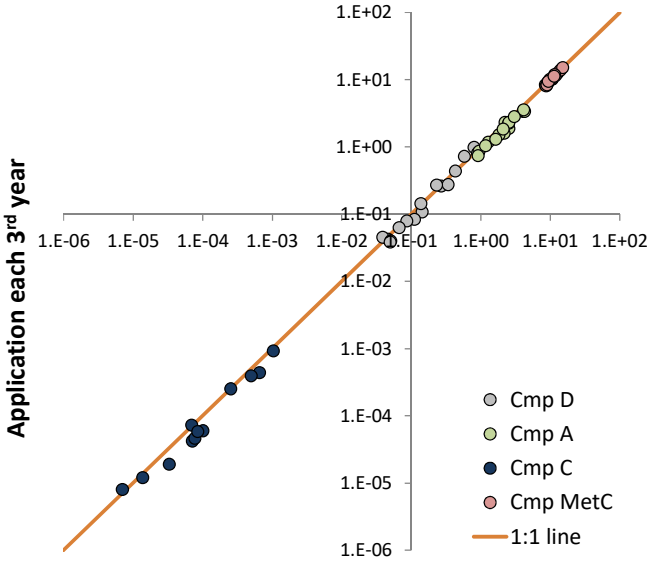


Figure B-1: Calculated *PEC*$_{GW}$ values (µg L^{-1}) for the FOCUS standard compounds A, D and C (including the metabolite Met-C) for the four FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster and Okehampton and for the crops maize, winter cereals, winter oil seed rape and potatoes (1 kg/ha 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.