

Zonal evaluation of applications for plant protection products

Recommendations for Core Assessments Section 5 Environmental Fate
zonal rapporteur member state Austria (zRMS AT)

General recommendations

According to the „Guidance Document on the Evaluation of New Active Substance Data Post Approval“ (SANCO/10328/2004-rev.8) the **endpoints established during the assessment for Annex I inclusion should be used for registration post Annex I inclusion**, unless new Annex II data

- are necessary in order to show a safe use,
- are “adverse” data (in the sense that no safe use is indicated).

Therefore, EU agreed endpoints given in the List of Endpoints (LoEP) of the Review Report or the EFSA Conclusion are required to be used for the risk assessment. In principal, the risk assessment should be performed as it was done in the EFSA conclusion. However, the latest versions of the FOCUS modelling shells should be used. In case that no EFSA conclusion is available, the Draft Assessment Report (DAR) should be taken into consideration. However in this case, **a common agreement on which input parameter will be used should be found in consultation with the zRMS (Pre-submission meetings)**.

If no safe use can be demonstrated based on the endpoints listed in the LoEP, a stepwise refinement of the input parameters can be done. It might be sufficient to start with one single parameter e.g. DT_{50} instead of including a completely new data package on degradation and adsorption. In general, a stepwise change of the parameters is recommended in order to comply with the LoEP as much as possible. If applicable new data should be combined with agreed Annex I endpoints.

If it is necessary to use new Annex II data for the risk assessment, the relevant studies should be summarised and discussed in the respective chapter of the dRR. The relevant study reports are to be provided to the zRMS. The data which has been already used for the Annex I inclusion should only be presented as short summary.

The risk assessment should be based on the critical GAP, whereas, the critical GAP might differ between the environmental compartments. All possibilities should be calculated, reported and the worst case scenario should be given in the respective chapter of the dRR.

For the PEC calculations, at the beginning of each chapter tables with the critical GAP, the input parameters used for modelling and maximum calculated PEC values should be presented.

Detailed recommendations

PEC soil (PEC_s)

- For reasons of completeness either a full study report on PEC_s calculations should be submitted or the calculation should be described in the dRR including all formulas used.
- PEC_s should be calculated only for the parent and for those metabolites that were considered for Annex I inclusion
- Plant interception values according to BBCH codes as defined in the FOCUS GW report or respective EFSA guidance should be used; if crop interception is not clear from BBCH codes (e.g. for multiple application) further information from the efficacy section might be necessary; otherwise assume minimum BBCH for all applications for conservative reasons
- The global maximum PEC_s should be given for each culture and indication.
- Justification should be given for the global maximum such as calculations for single/multiple, early/ late application.
- Use pseudo-application for metabolites corrected for maximum occurrence and molecular weight. The maximum occurrence of metabolites might be based on field data if these are of appropriate quality and cover the intended use.
- Kinetic formation approach for metabolites (similar to the groundwater risk assessment) can only be accepted as higher tier approach (worst-case situation for metabolites has to be ensured).
- Calculation should be based on a soil depth of 5 cm and a soil density of 1.5 g cm⁻³, other soil depths may be accepted if considered more appropriate for the GAP.
- Plateau concentration should be calculated on a basis of 20 cm (tilled areas, default) or 5 cm (non-tilled areas) of soil depth until equilibrium (plateau concentration) is reached; final PEC_s used for the risk assessment calculated on the basis of PEC_s (for one year, 5 cm or other appropriate soil depth) plus the PEC_s (plateau, 20 cm or 5 cm).
- Always use global maximum PEC_s for risk assessment (values may be different from PEC_s following the last application).
- TWA PEC_s should be calculated if considered necessary for risk assessment (e.g. TWA₂₁).

PEC groundwater (PEC_{GW})

- A study report on the PEC_{GW} calculation should be submitted only for the parent substance and for those metabolites that were considered for Annex I inclusion.
- Until further notice, all FOCUS groundwater scenarios should be calculated. Detailed description of each scenario is not necessary.
- Latest version of the FOCUS modelling tools should be used (currently FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS PRZM 3.5.2).
- If application timing is not clear from GAP, further information from the efficacy section might be necessary.
- Plant interception according to BBCH codes as defined in the FOCUS GW report or relevant EFSA guidance should be used; if crop interception is not clear from GAP (BBCH codes), information from the efficacy section might be necessary; otherwise assume minimum BBCH for all applications for conservative reasons
- The worst-case PEC_{GW} with respect to application rate and timing (early/late and spring/autumn application) should be given for each culture and indication.
- All modelling and substance input parameters should be given including:
 - Application scheme, type, rate and timing (if necessary scenario specific)
 - Plant uptake factor

PEC surface water /sediment (PEC_{SW/SED}):

- A study report of the PEC_{SW/SED} calculation should be submitted only for the parent substance and for those metabolites that were considered for Annex I inclusion.
- STEP 1, 2, 3 and 4 calculations should be done according to FOCUS (FOCUS surface water tool).
- Latest version of the FOCUS modelling tools should be used (currently STEP 1 and 2 v. 2.1, MACRO 5.5.3, PRZM 3.1.1, TOXSWA 3.3.1).
- PEC_{SW/SED} calculations are required for single and multiple applications and for early and late application interval.
- If application timing (appropriate application window) is not clear from GAP, further information from the efficacy section might be necessary.
- In case of STEP 4 calculations, modification of STEP 3 via the SWAN tool is accepted.
- Following mitigation measures are accepted:
 - Mitigation of drift by non-spray buffer zones: 5 m, 10 m, 15 m, 20 m, ...
 - Mitigation of run-off by vegetated filter strips: in line with the FOCUS landscape & mitigation report the following reduction factors are accepted (to be used for runoff/erosion water flux and a.i. flux as stated in SWAN; note: runoff water flux is additionally corrected by SWAN 1.1.4 for catchment area):
 - 10 m vegetated filter strip – 60 % water (factor = 0.6) / 85 % sediment (factor = 0.85),
 - 20 m vegetated filter strip – 80 % water (factor = 0.8) / 95 % sediment (factor = 0.95)
 - Mitigation by drift reducing nozzles: 50 %, 75 % and 90 %; the extend of drift reduction is considered constant over the entire distance.
- All modelling and substance input parameters should be given including:
 - Application method, application window (if necessary scenario specific)
 - Chemical application method (CAM)
 - Depth of incorporation
 - Plant uptake factor