



Abstracts

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Development of the Focus Groundwater Scenarios for the Assessment of the Leaching of Plant Protection Products in EU Registration

Jos Boesten, Alterra, jos.boesten@wur.nl, CC +31317481620

Russel L. Jones, Bayer CropScience, russell.jones@bayercropscience.com, +1 919 433 5487

In 1993, the European Commission initiated the Forum for the Co-ordination of pesticide fate models and their use (FOCUS). The aim was to harmonize the calculation of predicted environmental concentrations of active substances of plant protection products in the framework of the EU registration procedure. FOCUS is based on co-operation between scientists of regulatory agencies, academia and industry. Since then three FOCUS workgroups have been developing guidance for leaching to groundwater (1993-1995, 1997-2000 and 2004-2009). Also for other environmental compartments, FOCUS workgroups were established. Around 2007, the European Commission transferred the responsibility for developing guidance for environmental risk assessment to the European Food Safety Agency (EFSA), so FOCUS is now finalizing its activities. The first groundwater workgroup agreed on a terminology for crucial terms such as validation status of a model and made an inventory of existing leaching models. The second groundwater workgroup aimed at developing a limited number of scenarios. This workgroup divided the EU into a number of climatic zones and developed a scenario for each of these zones. This procedure was adopted because the EU registration procedure is based on the principle of a safe use of a sufficient size. So the consequence is that the use does have to be safe only in part of the climatic zones for a positive decision at EU level. Within each zone, the aim was to select a realistic worst case scenario which was specified as a 90th percentile case (considering both soil and weather as drivers for the vulnerability). The selection of the soil profiles had to be based on local experts and expert judgment because a pan-European soil database was not available. This led to the release of nine FOCUS groundwater scenarios at the end of 2000 (Figure 1). These scenarios are software packages that each contain a numerical model (PRZM, PELMO or PEARL), a database and a user interface, enabling leaching calculations for these nine scenarios (additionally there is also a software package for the MACRO model for one of these nine scenarios). Since their release these software packages have been under strict version control and all released packages are still available for downloading (<http://focus.jrc.ec.europa.eu>). Among EU regulators the FOCUS groundwater scenarios are considered to be a successful example of harmonization within the EU registration procedure. The third FOCUS groundwater workgroup was put into life (i) to develop tiered leaching assessment schemes for EU and national levels (see Figure 2), (ii) to improve the parameterization of the existing nine Tier-1 scenarios in view of experiences gained in R&D projects and in the EU registration procedure, (iii) to develop the role of higher-tier modeling and higher-tier experiments (such as lysimeter studies, the use of spatial data in assessments, and incorporation of non-equilibrium sorption) in the leaching assessment, (iv) to assess whether these nine scenarios were still sufficient after the EU was enlarged from 15 to 25 Member States. The report of the third workgroup has been submitted for review to EFSA in summer 2009.

Figure 1. Locations of the nine FOCUS groundwater scenarios.

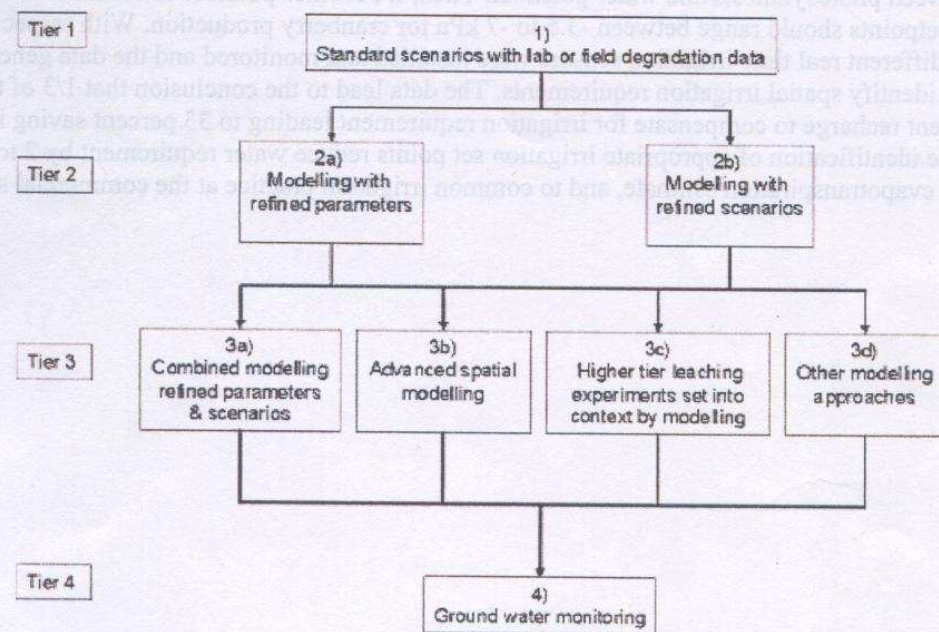


Figure 2. Proposed generic tiered assessment scheme for leaching of plant protection products to groundwater.