

Context setting of plant protection product monitoring data for EU-wide, zonal and national registration

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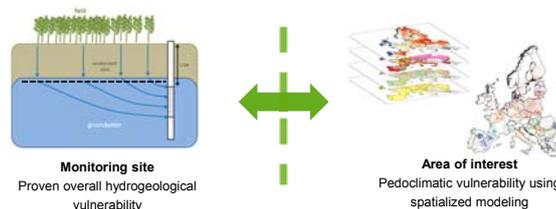
Introduction

In the EU active substance and product registration process, the **assessment of the risk for contamination of groundwater** follows a **tiered approach** to establish if **safe-uses exist in the area of interest**.

This concept and the associated methodology is well established in the lower tiers of the assessment scheme (modeled leaching concentrations are compared to defined threshold in relevant modeling scenarios). However in the highest tier of this scheme, relying **on monitoring data**, the demonstration of representative safe uses considering data from a collection of field leaching studies or groundwater monitoring sites is new.

A methodology was developed to contextualize targeted monitoring data or field leaching studies to demonstrate their **applicability at a larger scale of interest** (i.e. EU, zonal or national) and thus allow assessment of a representative safe use. It relies on **spatially distributed modeling** of leaching to groundwater in combination with measurements from groundwater wells in **hydrogeologically highly vulnerable situations** (e.g. shallow porous aquifers).

Figure 1: General approach of the contextualization methodology



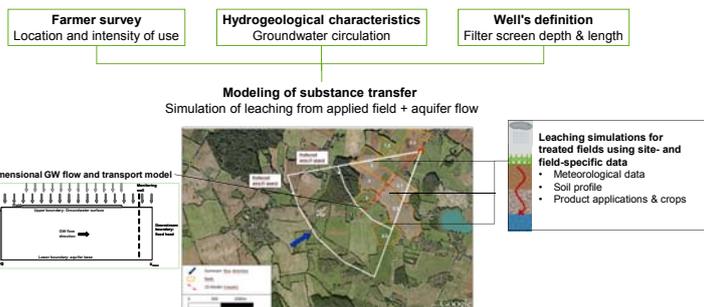
Vulnerability of monitoring sites

Establishing the overall vulnerability of the monitoring sites

The vulnerability of the sites should be demonstrated according to the EU quality criteria (FOCUS, 2014)

- **Sufficient use of products** on fields in the topographical catchment of the well
- **Connectivity** of the applied surfaces with the monitoring wells
- **Sampling duration and frequency** adapted to solute transfer time

While indications can give a general idea of the vulnerability of the site (shallow aquifer and/or sampling point, indication of past contamination linked to local uses), detailed data are necessary to assess the quality criteria.



From these coupled simulations using simulated leaching concentrations below treated fields as boundary conditions for 2D flow and transport simulations in the aquifer

- **Connectivity** demonstrated by acceptable description of concentrations' dynamic
- **Sampling duration and frequency** adequate if sampled concentrations cover modeled peaks in value and duration.

Pedoclimatic vulnerability

Contextualization of the vulnerability of the wells

The specific pedoclimatic conditions of the sites for leaching vulnerability need to be contextualized for the area of interest.

This can be achieved by conducting **spatialized leaching simulations** considering relevant pedoclimatic variables and substance parameters.

In this work we used MetaPEARL, the metamodel of the spatialized mechanistic leaching model EuroPEARL:

- The model considers relevant pedoclimatic data (P, T, %OM, p...) and substance parameters (half-life, K_{om}).
- Input data and simulations are set-up through GIS layers (flexible source selection, specific crops).
- MetaPEARL is proposed as an higher-tier option in the FOCUS GW guidance document (FOCUS, 2014)

Using MetaPEARL, the relative leaching concentrations of the monitoring sites within this area of interest illustrate their **relative coverage** of the general pedoclimatic vulnerability.

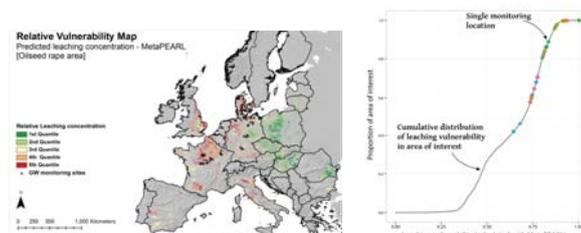


Figure 2: Example of leaching risk contextualization for application on Oilseed rape in Europe as color-coded quartiles (left) and relative concentrations distribution (right)

Conclusions & perspectives

- Consideration of highly vulnerable, well documented, monitoring sites according to the EU quality criteria **compensates** for the absence of **EU-wide** hydrogeological data.
- The **combination of local vulnerability assessments and spatialized leaching modeling** developed in this method allows for **extending** conclusions obtained in the specific pedoclimatic conditions of the monitoring sites to a much larger **regulatory area of interest** (whole EU, zonal, national)
- The contextualization step is **relatively flexible**, and could also be applied to FOCUS scenario climatic zones to link the coverage of the monitoring sites to scenarios used in the lower tiers of the FOCUS GW risk assessment scheme. This would provide a **simple criteria** for establishment of **safe uses**.
- Discussion within the regulatory community might be needed regarding the **expected pedoclimatic coverage** of monitoring sites (worst-case, homogeneous coverage...)