

Guidance from FOCUS workgroups for leaching of plant protection products to groundwater in EU registration

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Outline

- introduction to EU policy and FOCUS
- FOCUS groundwater workgroups
- main FOCUS achievements with respect to groundwater
- key consequences for policy makers



Introduction to EU policy for plant protection products in groundwater

- in EU legislation pesticides = plant protection products
- basis: Uniform Principles (Annex VI to Directive 91/414/EEC)
- UP in 1994: maximum groundwater concentration of 0.1 µg/L for parent compounds and for relevant metabolites
 - concept: groundwater free of pesticides
 - 0.1 µg/L was detection limit in 1980 when this criterion was established
 - separate guidance document for metabolites



Introduction to EU policy for plant protection products in groundwater

- 0.1 µg/L is a very low concentration
 - mass fraction of 10⁻¹⁰ (one gram in ten million litres or 10 000 m³ water)
 - corresponds to 0.01% of pesticide dose of 1 kg/ha in 100 mm of leachate
- registration of pesticide in EU consists of two steps
 - active ingredient of pesticide at EU level
 - formulated products at Member State level
- risk assessment procedure at EU level:
 - registrant submits a dossier (including leaching assessment)
 - one Member State is rapporteur: summarizes of the dossier
 - European Food Safety Agency responsible for review of summary by other Member States



Introduction to FOCUS

- **FO**rum for **Co**-ordination of pesticide fate models and their **US**e
- founded in 1992: co-operation between European Commission and European Crop Protection Association (ECPA)
- aim of FOCUS:
 - Guidance for environmental fate modelling in context of Annex VI of Directive 91/414/EEC ("... estimate, **using a suitable calculation model** validated at Community level, the concentration...")
- basis for FOCUS: modelling approach proposed by political level (Annex VI of Directive 91/414/EEC)
- FOCUS started developing guidance for EU level but after some ten years widened its scope to Member State level



Introduction to FOCUS

- organisation:
 - steering committee
 - European Commission
 - political representatives from six EU Member States
 - ECPA
 - two meetings per year
 - workgroups
 - scientists from academia and industry
 - well defined tasks (develop guidance based on existing knowledge)
 - in a limited period (few years)
 - scientific consensus

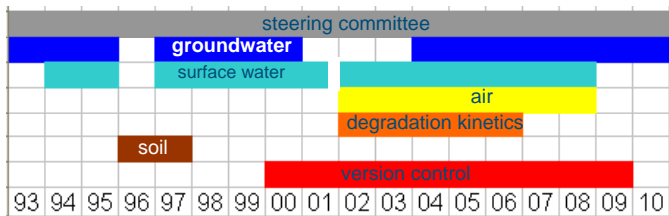
FOCUS Steering Committee



FOCUS workgroups



FOCUS organisation from 1993 to 2010



FOCUS ends now: European Commission transferred responsibility for pesticide risk assessment in 2007 to the European Food Safety Agency (EFSA) in Parma (Italy)



Three FOCUS groundwater workgroups

- 1993-1995: agreed terminology (eg validation status of a model) and made inventory of existing leaching models
- 1997-2000: developed nine groundwater scenarios for European Union (EU-15)
- 2004-2009:
 - (i) develop tiered assessment schemes
 - (ii) improve parameterisation of existing nine scenarios
 - (iii) develop role of higher tier modelling and higher tier experiments
 - (iv) assess whether scenarios are still OK for EU-27



FOCUS groundwater workgroups

1997-2000



2004-2009



- about 15 persons:
 - 4 from ag chem industry (ECPA)
 - 3 from registration authorities
 - 8 from universities or research institutes



Main FOCUS achievements related to groundwater

- nine FOCUS groundwater scenarios for three pesticide leaching models (PRZM, PELMO and PEARL)
 - first versions in 2000
 - revised versions in 2009
 - sufficient also after enlargement from EU-15 to EU-27
- adequate version control and free availability of software packages at FOCUS website
- generic tiered assessment scheme
- role of higher tier modelling and higher tier experimental data



FOCUS groundwater scenarios

- EU (15 Member States in 1998) divided into a number of climatic zones
- 'realistic worst-case' scenarios for each zone
 - 90th percentile
- political background: EU registration based on principle of safe use of sufficient size
- tailored to political needs: no need to be safe under all climatic conditions



FOCUS groundwater scenarios

- simplified approach to assess 90th percentile scenario
 - 1998: do it as best as you can, but do it!
 - combine 80th percentile soil with 80th percentile weather period
 - many GIS data are not publicly available in EU: expert judgement needed to select soils
- user-friendly software packages of PRZM, PELMO and PEARL models
 - numerical model + database + user interface
 - easy to calculate leaching for all scenarios
 - additionally MACRO model for one of the nine scenarios



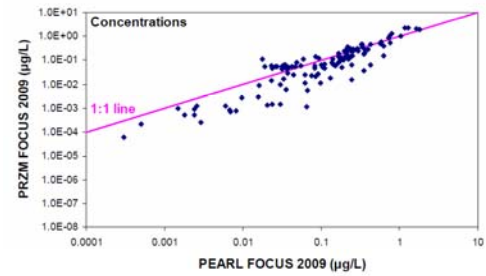
FOCUS groundwater scenarios

- 125 location-crop combinations
 - 9 locations
 - 25 crops
- scenarios used since late 2000
- 2009: revisions proposed:
 - improvements in definitions of scenarios
 - changes in model parameterisation to increase harmonisation between PRZM-PELMO-PEARL model

Scenario	Crop	C	M	W	S	N	E	S	N	E	S	N	E	S	N	E
Scenario 1	Crop 1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 2	Crop 2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 3	Crop 3	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 4	Crop 4	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 5	Crop 5	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 6	Crop 6	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 7	Crop 7	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 8	Crop 8	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 9	Crop 9	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 10	Crop 10	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 11	Crop 11	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 12	Crop 12	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 13	Crop 13	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 14	Crop 14	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 15	Crop 15	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 16	Crop 16	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 17	Crop 17	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 18	Crop 18	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 19	Crop 19	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 20	Crop 20	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 21	Crop 21	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 22	Crop 22	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 23	Crop 23	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 24	Crop 24	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Scenario 25	Crop 25	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

FOCUS groundwater scenarios

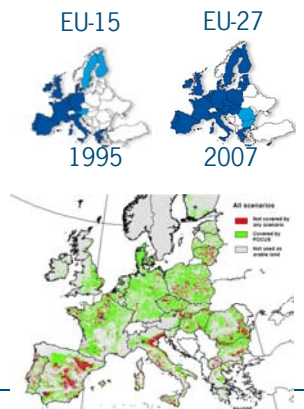
Leaching concentrations ($\mu\text{g/L}$) of pesticide "D"



Example PRZM and PEARL calculations for a hypothetical pesticide and all 125 crop-location combinations: considerable improvement of correspondence in 2009 compared to 2000

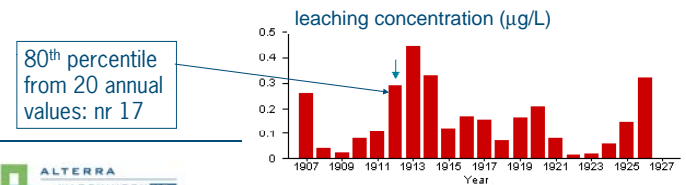
FOCUS groundwater scenarios

- nine scenarios released in 2000 for EU-15 but now EU-27
- do these scenarios also cover new member states?
 - not covered if more rainfall or less organic matter than existing scenarios
- GIS analysis: scenarios are OK for new member states



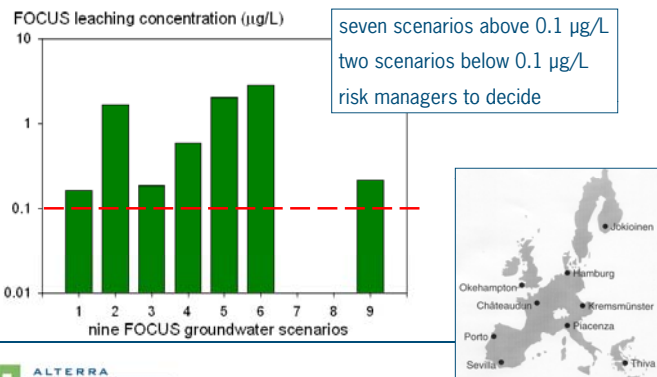
FOCUS groundwater scenarios

- example case: assessment of leaching of hypothetical pesticide
 - using basic properties from registration dossier
 - $DegT50 = 30$ d (top soil at 20°C at field capacity)
 - $K_{OM} = 50$ L/kg
- applied in winter wheat just before emergence at 1 kg/ha
 - winter wheat grown every year
- models calculate annual average leaching concentration at 1 m depth
 - time series of 20 years for application every year



FOCUS groundwater scenarios

Results for this example case (calculated with PEARL)



FOCUS version control of models and scenarios

- Strict version control of all software packages
 - based on detailed agreed protocol (2000)
 - leaching calculations performed by registrant and submitted in registration dossier
 - must be easily duplicated by registration authorities



Availability of models and scenarios

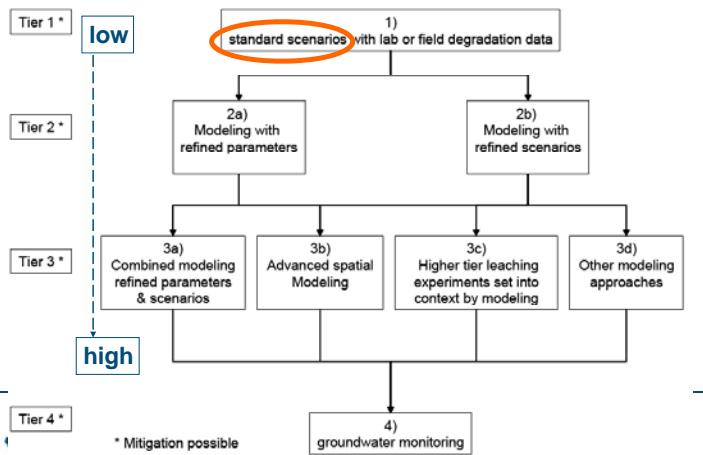
- separate FOCUS workgroup for version control and FOCUS website (2000-2009)
 - responsibility taken over by EFSA version control workgroup
- all past and current software packages freely downloadable from the FOCUS website
 - <http://focus.jrc.ec.europa.eu/>
- also all documents available



Generic assessment scheme for leaching

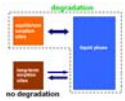
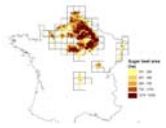
- generic: both for leaching at EU level and at Member State level
- tiered approach because cheapest both for industry and registration authorities
- principles of tiered approaches:
 - concept: do not more than necessary
 - lower steps more conservative than higher steps
 - higher steps more realistic than lower steps

Generic tiered assessment scheme for leaching



Higher tier modelling approaches and higher tier experimental data

- guidance for GIS based approaches for creating crop specific scenarios
- information on European-wide data sets for GIS analysis
- guidance for implementing non-equilibrium sorption in scenario calculations
- guidance on inverse modelling approaches combining results of field or lysimeter studies with modelling
- discussion of design of lysimeter studies, field leaching studies and ground water monitoring studies and their role in tiered assessment scheme



Key consequences for policy makers

context: groundwater risk assessment problem that is solvable with sophisticated scientific methods (including software packages)

- you have to be committed to development of science-based tools over a period of at least three years
 - investing time in adequate communication with the scientists is crucial
 - eg meet with scientists twice per year
- let scientific workgroups agree via scientific consensus but give them limited time and instruct them to solve the problem based on available knowledge
 - no escapes to years of research before problem can be solved
- ensure adequate version control and free availability of software packages

Thank you for your attention !

