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

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Bayer CropScience

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

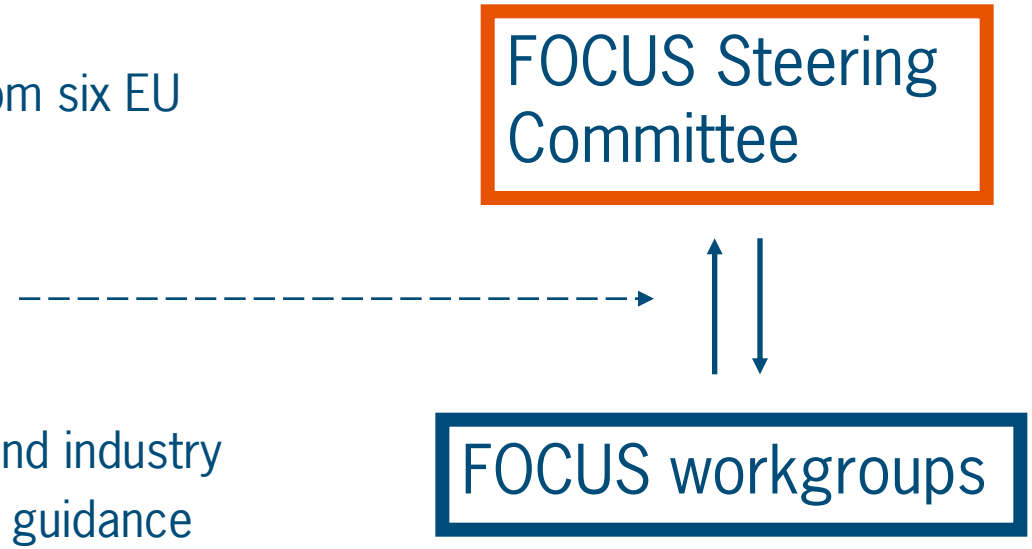
- 0.1 µg/L is a very low concentration
  - mass fraction of 10^{-10} (one gram in ten million litres or 10 000 m^3 water)
  - corresponds to 0.01% of pesticide dose of 1 kg/ha in 100 mm of leachate
- registration of pesticide in EU consists of two steps
  - active ingredient of pesticide at EU level
  - 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

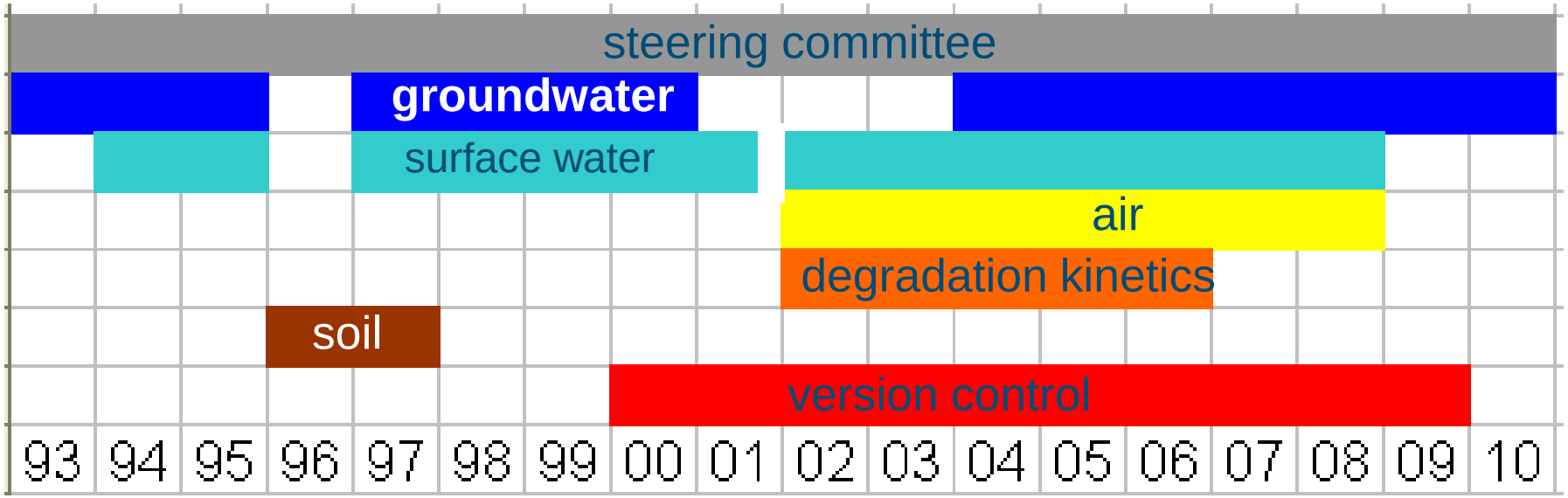
- **FO**rum for **C**o-ordination of pesticide fate models and their **US**e
- founded in 1992: co-operation between European Commission and European Crop Protection Association (ECPA)
- aim of FOCUS:
  - Guidance for environmental fate modelling in context of Annex VI of Directive 91/414/EEC ("… estimate, **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 organisation from 1993 to 2010



FOCUS ends now: European Commission transferred responsibility for pesticide risk asssessment 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

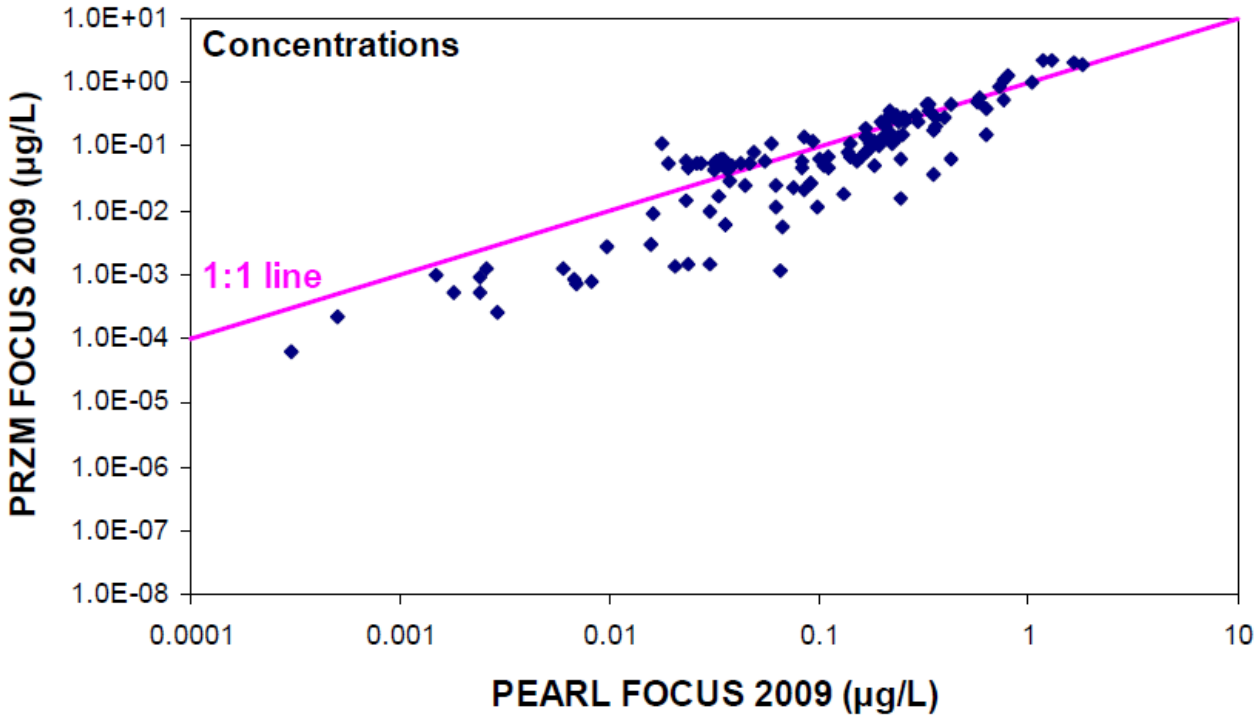
FOCUS groundwater scenarios

- 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

Crop	C	H	J	K	N	P	O	S	T
apples	+	+	+	+	+	+	+	+	+
grass (+ alfalfa)	+	+	+	+	+	+	+	+	+
potatoes	+	+	+	+	+	+	+	+	+
sugar beets	+	+	+	+	+	+	+	+	+
winter cereals	+	+	+	+	+	+	+	+	+
beans (field)		+		+	+				
beans (vegetables)							+		+
bush berries			+						
cabbage	+	+	+	+			+	+	+
carrots	+	+	+	+			+		+
citrus						+	+	+	+
cotton								+	+
linseed					+				
maize	+	+		+	+	+	+	+	+
oil seed rape (summer)	+		+		+		+		
oil seed rape (winter)	+	+		+	+	+	+		
onions	+	+	+	+			+		+
peas (animals)	+	+	+		+				
soybean						+			
spring cereals	+	+	+	+	+		+		
strawberries		+	+	+				+	
sunflower						+		+	
tobacco						+			+
tomatoes	+					+	+	+	+
vines	+	+		+		+	+	+	+

FOCUS groundwater scenarios

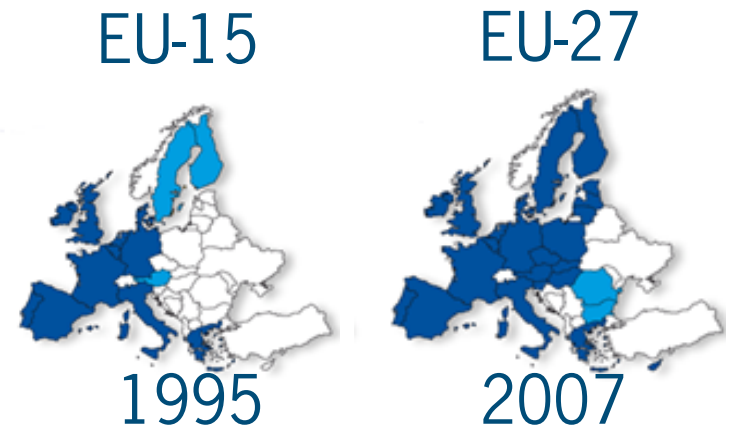
Leaching concentrations (µg/L) of pesticide "D"

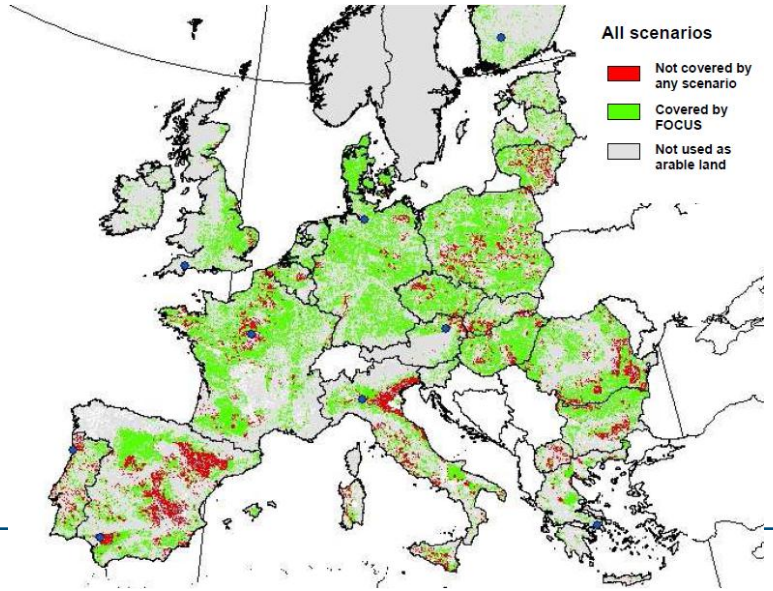


Example PRZM and PEARL calculations for a hypothetical pesticide and all 125 crop-location combinations: considerable improvement of correspondence in 2009 compared to 2000

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

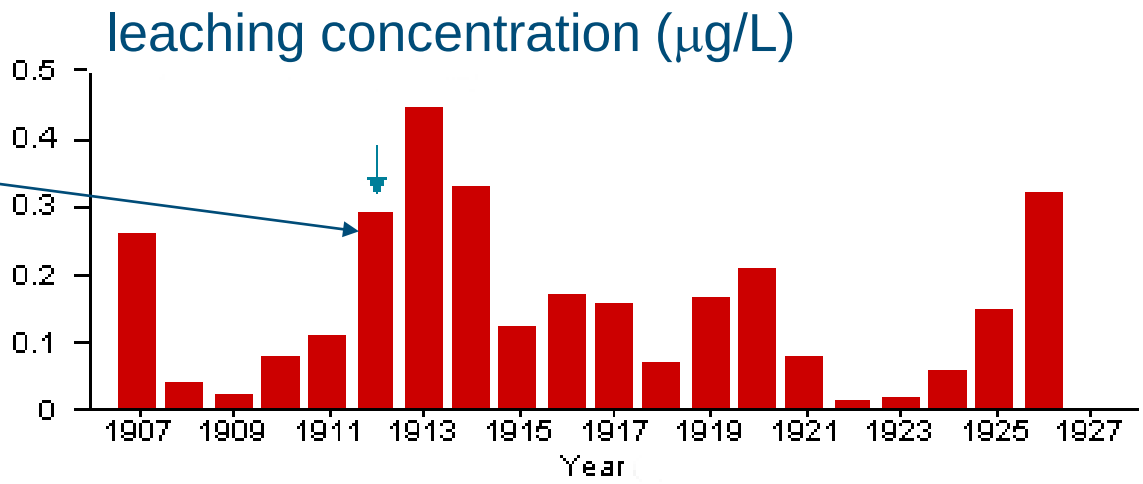




FOCUS groundwater scenarios

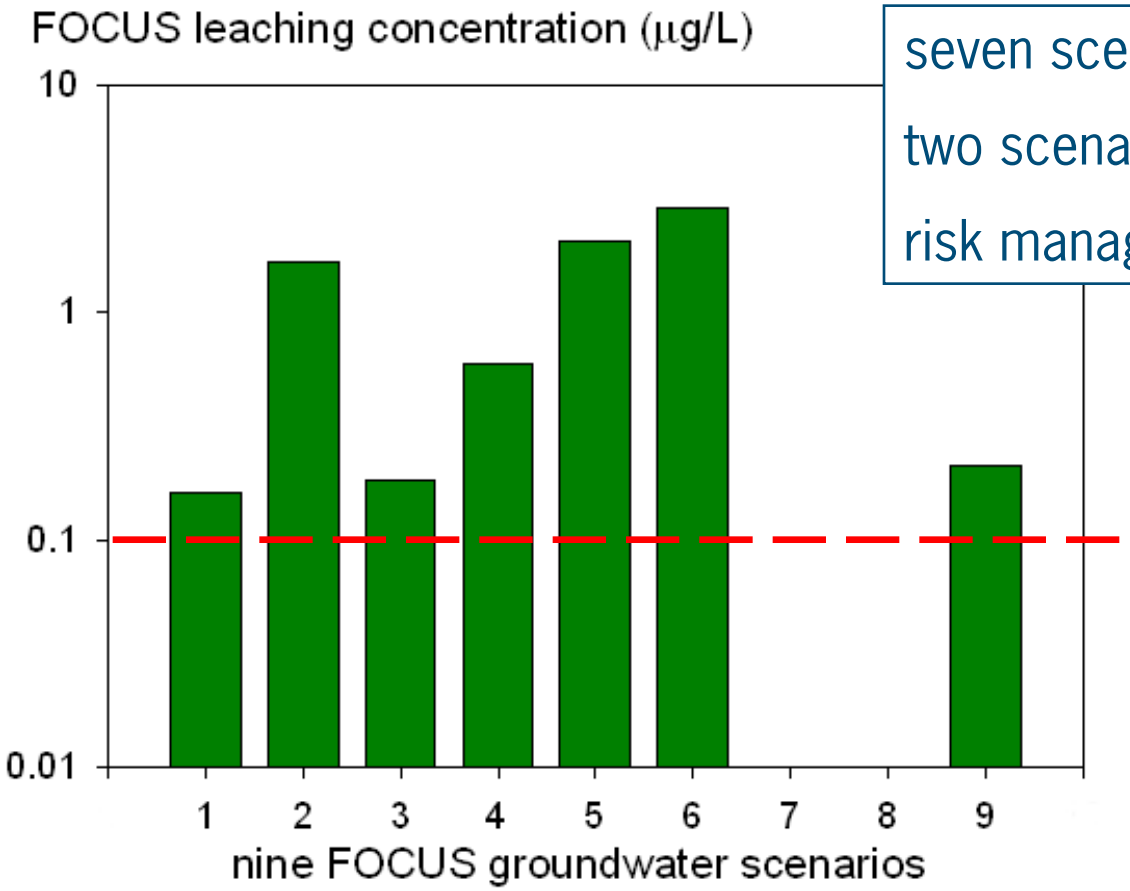
- example case: assessment of leaching of hypothetical pesticide
  - using basic properties from registration dossier
  - *DegT50* = 30 d (top soil at 20°C at field capacity)
  - K_{OM} = 50 L/kg
- applied in winter wheat just before emergence at 1 kg/ha
  - winter wheat grown every year
- models calculate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

80th percentile from 20 annual values: nr 17



FOCUS groundwater scenarios

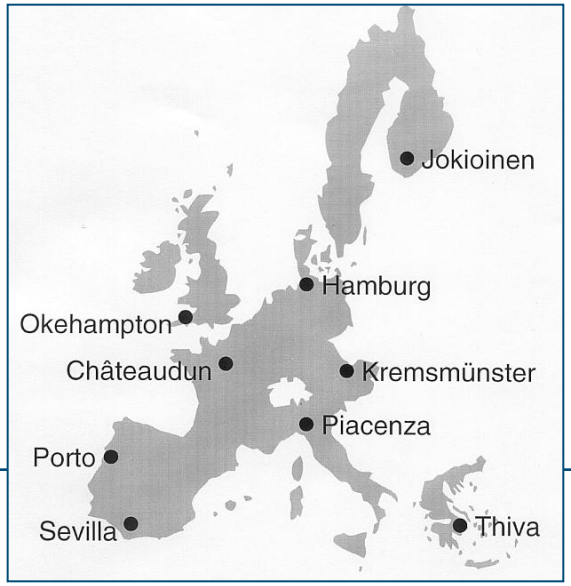
Results for this example case (calculated with PEARL)



seven scenarios above 0.1 µg/L

two scenarios below 0.1 µg/L

risk managers to decide



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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

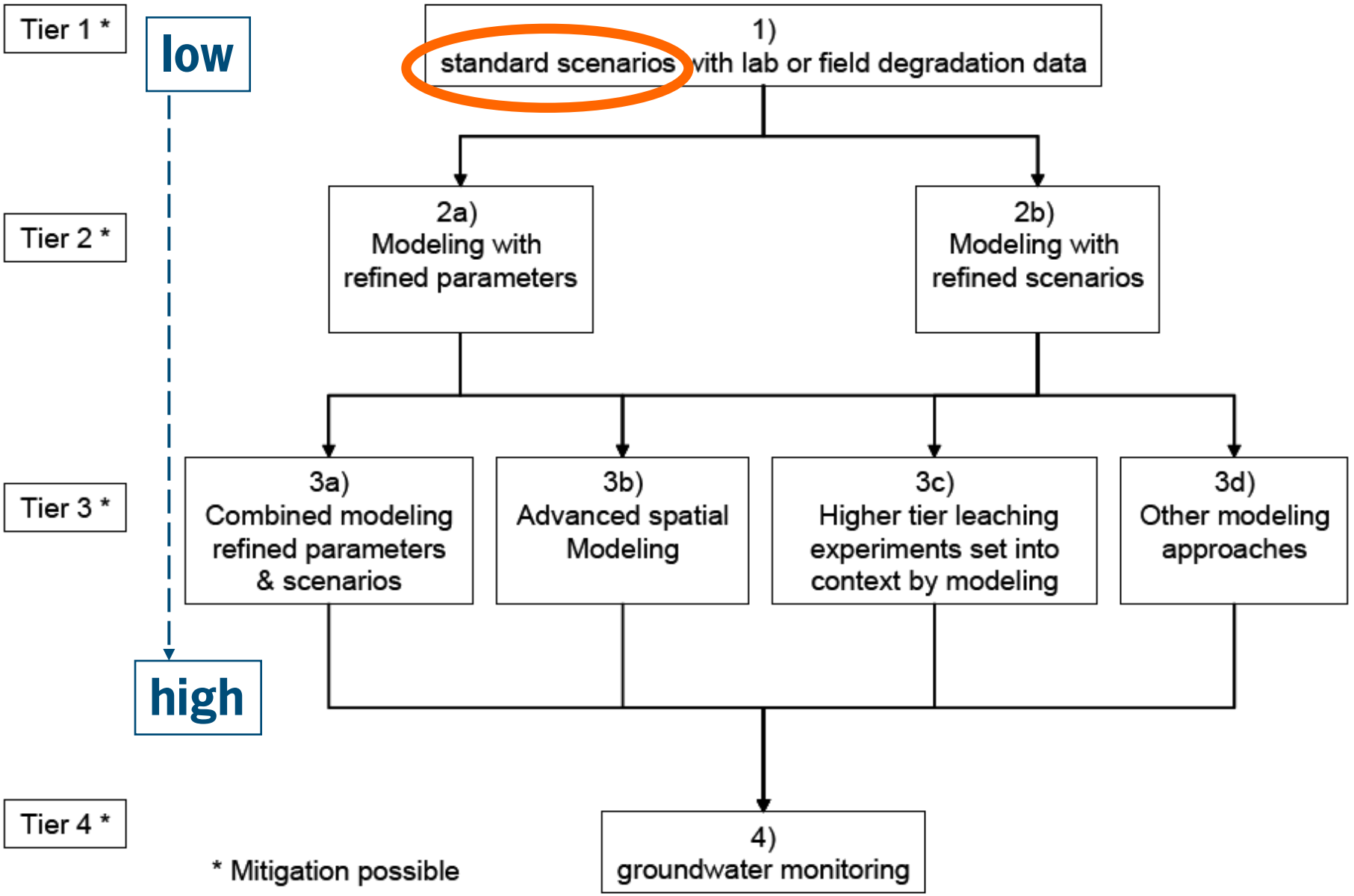
Availability of models and scenarios

- 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

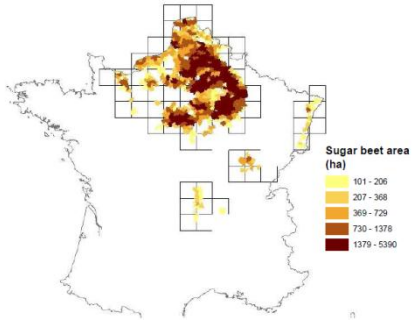
Generic assessment scheme for leaching

- 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

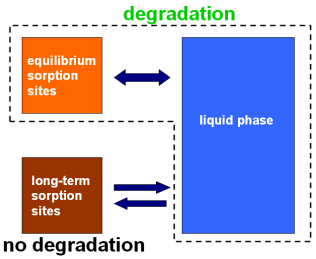
Generic tiered assessment scheme for leaching

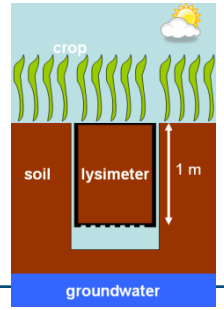


Higher tier modelling approaches and higher tier experimental data



- 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 !

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