

# Registration Procedure of Plant Protection Products in Europe

Paul J. Van den Brink

(thanks to Theo Brock,, Steve Maund and Paulien Adriaanse)  
Alterra, Wageningen University, Wageningen, The Netherlands  
[Paul.vandenBrink@wur.nl](mailto:Paul.vandenBrink@wur.nl)



## Prospective Risk Assessment



## Prospective Risk Assessment

### ■ What do we want to protect?

- In **human risk assessment** it is the individual that needs to be protected
  - Occupational health risks when applying pesticides
  - Risks via contamination of drinking water and food
  - Risks of accidental contacts with e.g. obsolete stocks
- **Ecological risk assessment** aims to guarantee a **sustainable management** of ecosystems and the focus usually is on populations and communities of flora and fauna



## Prospective Risk Assessment

### Concepts to evaluate the acceptability of risks

- **The Pollution Prevention Principle**
  - All environmental pressure is potentially harmful
- **The Ecological Threshold Principle**
  - Communities and sensitive populations are hardly impacted below a certain threshold level
- **The Community Recovery Principle**
  - Populations usually recover from stress by non-persistent chemicals
- **The Functional Redundancy Principle**
  - Decrease in biodiversity needs not to be dramatic due to redundancy in functions of surviving species



## Risk Assessment of Pesticides

### Legal Framework

- Situation in the EU regarding plant protection products:
- Directive 2009/1107/EC
  - annex I - List of active substances
  - annex II - Data requirements for active substance
  - annex III - Data requirements for formulated product
    - microcosm and mesocosm tests
  - annex V - Safety phrases
  - annex VI - Uniform principles of risk assessment
    - „unless“ - clause
- Guidance Document on Aquatic Ecotoxicology

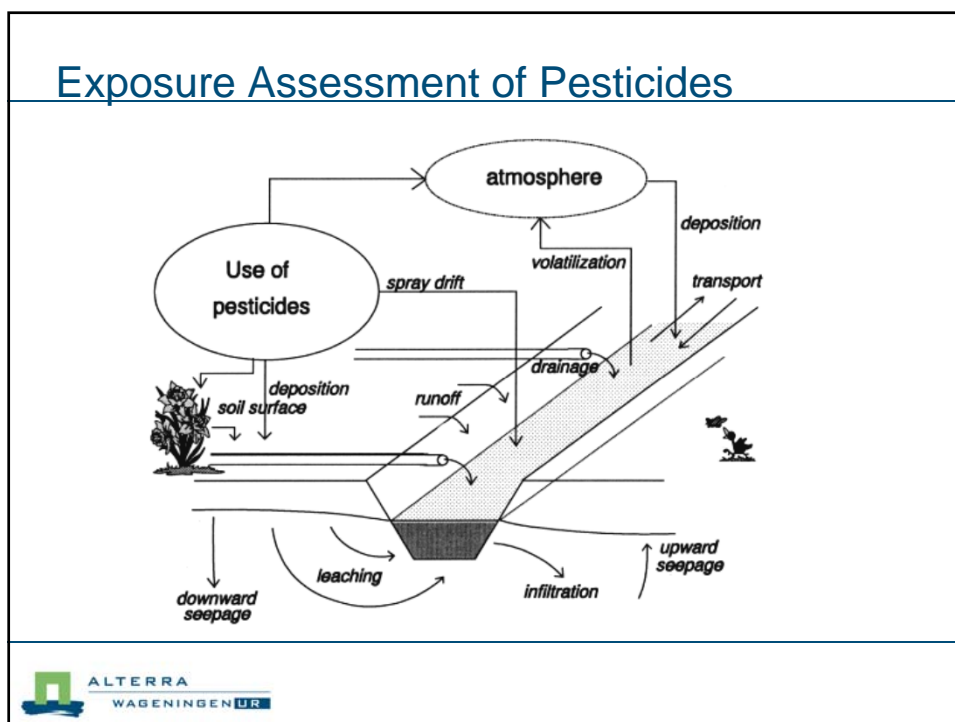
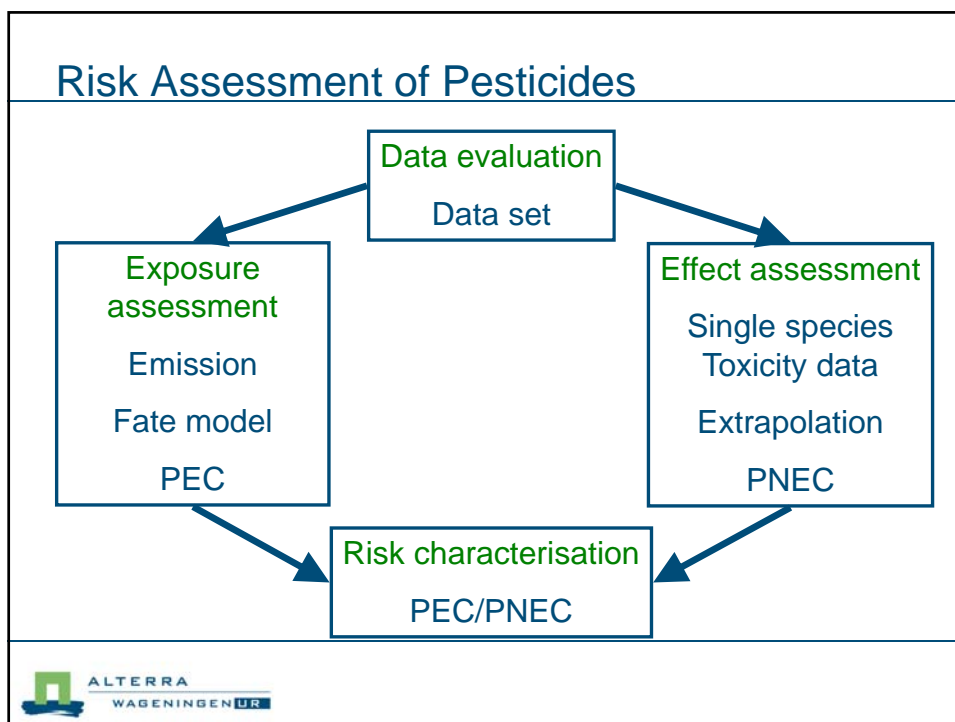


## Risk Assessment of Pesticides

### Legal Framework

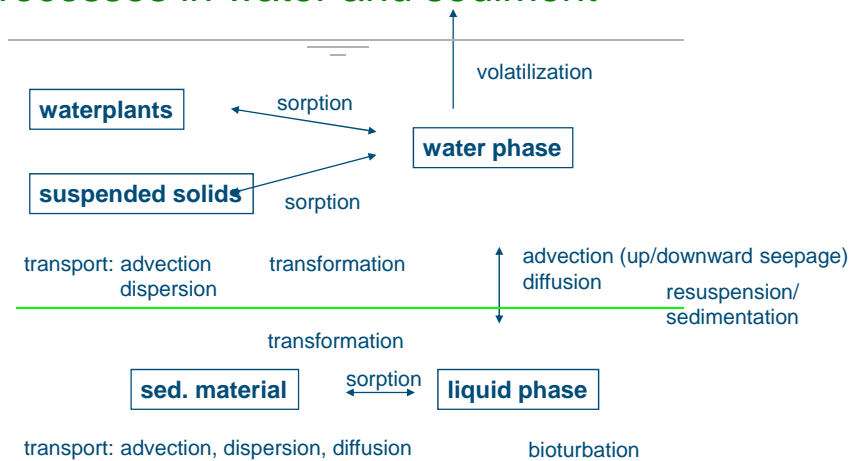
- Industry provides required data
- One of the regulatory bodies performs risk assessment at the EU level
- After registration in EU, registration for (groups of) individual countries can be requested





## Exposure Assessment of Pesticides

### Processes in water and sediment



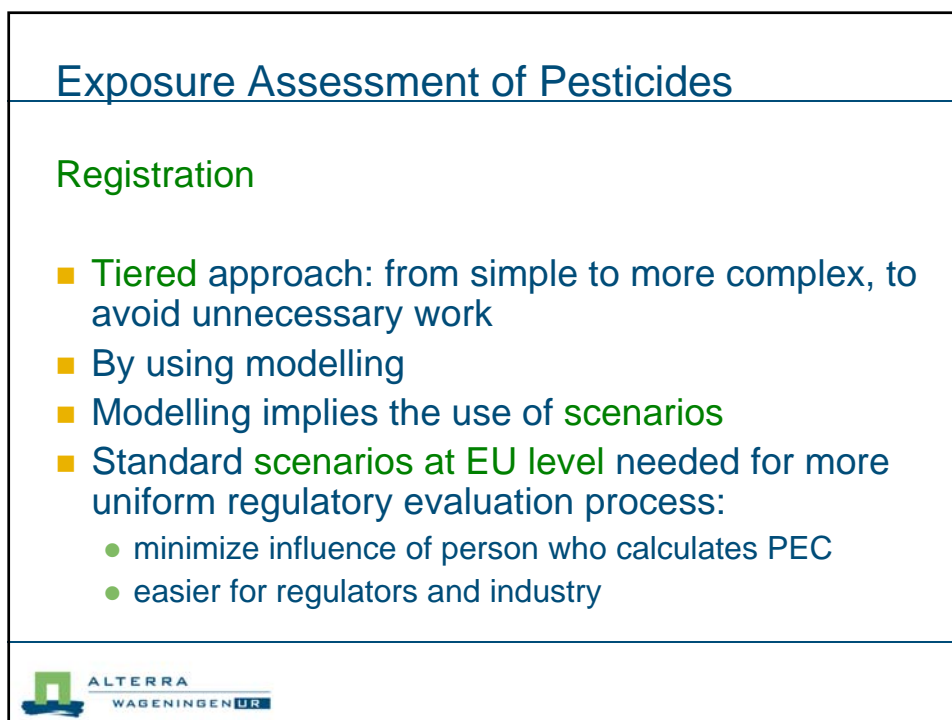
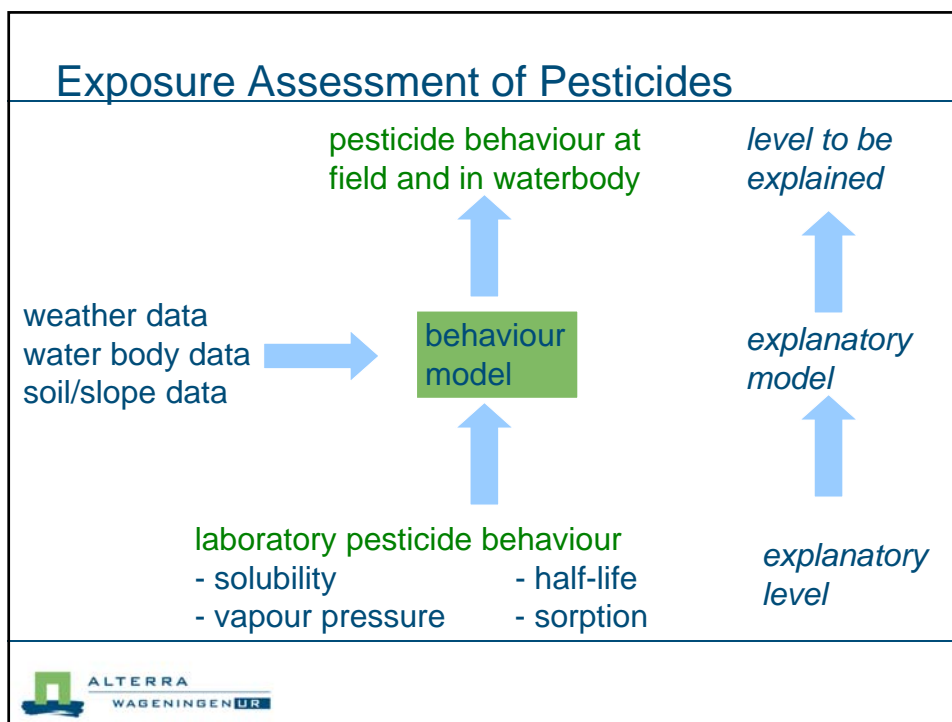
## Exposure Assessment of Pesticides

### ■ Problems:

- > 100 pesticides registered
- each country large variation in water bodies, weather
- at EU level variation even larger
- measurements: expensive and slow

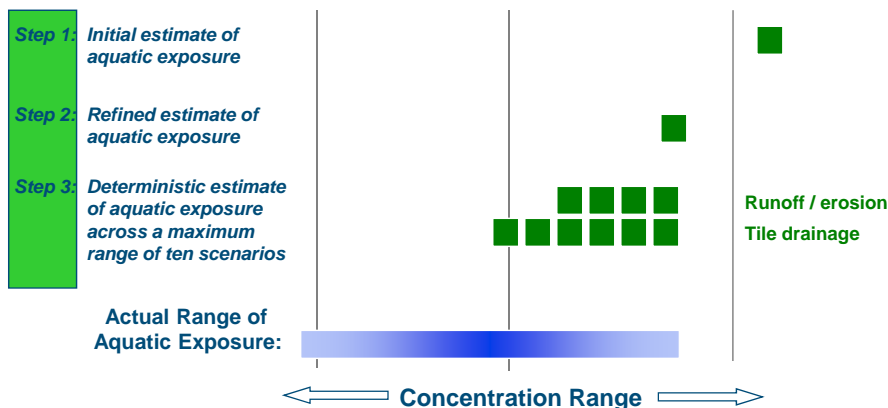
### ■ Modelling:

- knowledge from one pesticide applicable to others
- effects of other conditions
- cheap and fast
- based on lab studies (available in dossiers)



## Exposure Assessment of Pesticides

### Exposure Estimate



## Exposure Assessment of Pesticides

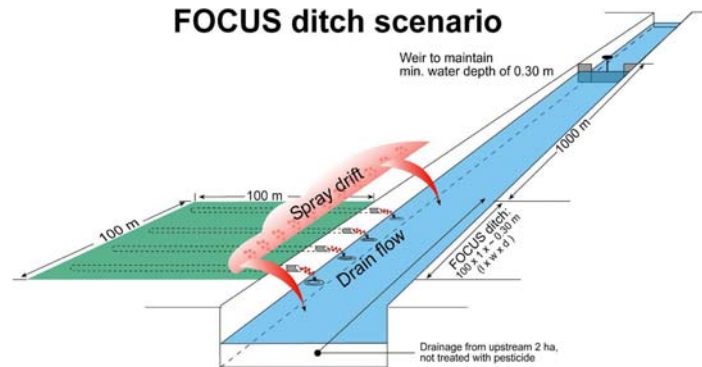
### Step 3: scenario definition

- FOCUS approach for realistic worst case:
  - define major agricultural areas within EU
  - select 90th percentile vulnerable scenarios within each area
- No theoretically correct statistical approach (hundreds of scenarios needed)
- Pragmatic approach for realistic worst case:
  - agro-environmental conditions (climate, slope, soil)
  - spray drift entries (overall 90th percentile)
  - drainage/runoff entries (50-70th percentile)
  - entries from upstream catchment into FOCUS waterbodies (ditch, stream and pond)

## Exposure Assessment of Pesticides

### ■ Scenarios

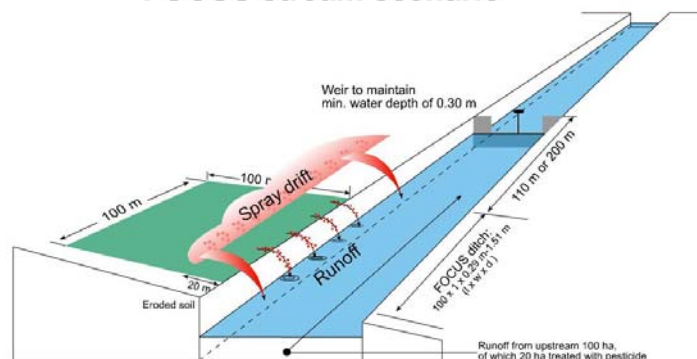
#### FOCUS ditch scenario



## Exposure Assessment of Pesticides

### ■ Scenarios

#### FOCUS stream scenario

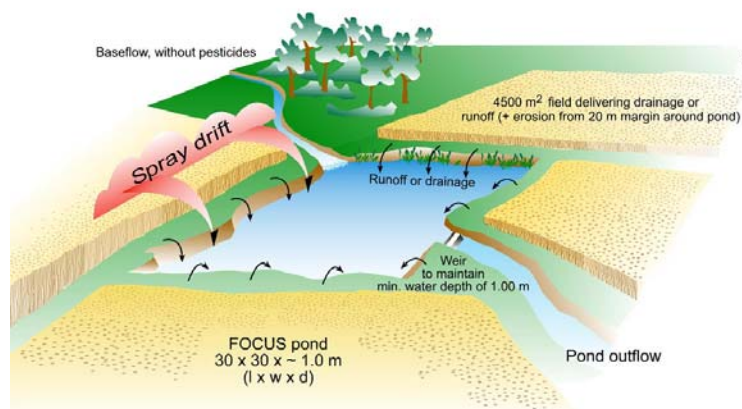




## Exposure Assessment of Pesticides

### ■ Scenarios

#### FOCUS pond scenario



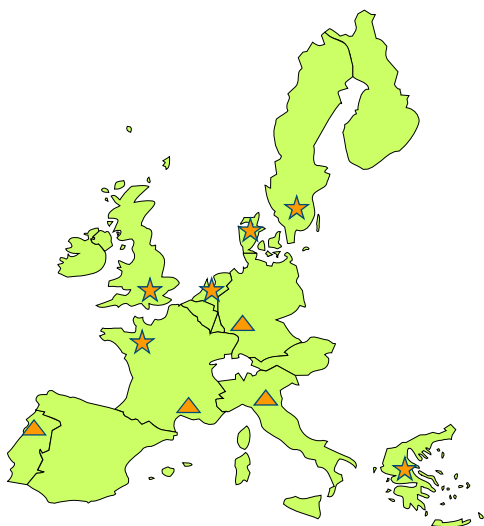
## Exposure Assessment of Pesticides

### Drainage and drift ★

Sweden	ditch, stream
UK	ditch, stream
Netherlands	ditch
Denmark	pond, stream
France	stream
Greece	ditch, pond

### Runoff, erosion and drift ▲

Germany	pond, stream
Portugal	stream
Italy	stream
France	stream



## Exposure Assessment of Pesticides

### Tools for Step 3 assessment:

- FOCUS drift calculator (BBA, 2000)
- PAT, Pesticide Application Timer (in MACRO, PRZM)
- MACRO (for D scenarios)
- PRZM (for R scenarios)
- TOXSWA (fate)
- SWASH, overall specific FOCUS sws shell



## Exposure Assessment of Pesticides

### Step 4: risk refinement and mitigation:

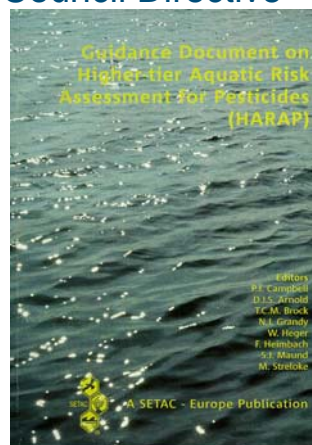
- Possible risk refinement steps:
  - site-specific modelling (entries, characteristics water)
  - more rigorous probabilistic modelling
  - landscape modelling (e.g. GIS for distance crop-water)
  - field studies, higher-tier ecotox studies
- Possible mitigation steps:
  - reduction of spray drift (e.g. nozzles, buffers)
  - reduction of runoff or drainage (e.g. buffers, tillage)
  - ecological considerations



## Effect Assessment of Pesticides

### ■ Tiered effect assessment under Council Directive 91/414/EEC:

- Standard toxicity tests
- Modified exposure studies
- Additional single species studies (SSD)
- Microcosms
- Mesocosms
- Modelling
  - Metapopulation modelling
  - Foodweb modelling



## Effect Assessment of Pesticides

### Tier 1:

- **Standard assessment**
  - laboratory single-species tests (acute, chronic)
  - algae, daphnia, fish, sediment-dwelling organisms, higher aquatic plants
  - bioaccumulation
  - active substance, formulated product, metabolites
- **EC50, NOEC, ECx for the most sensitive organism**
- **Risk assessment:**
  - **Acute:**  $EC_{50} / PEC > 100$
  - **Chronic:**  $NOEC / PEC > 10$

## Further evaluation

- Authorization cannot be granted unless it can be demonstrated that under field conditions, the compound will not pose unacceptable risks to aquatic populations
- Higher tier risk assessment

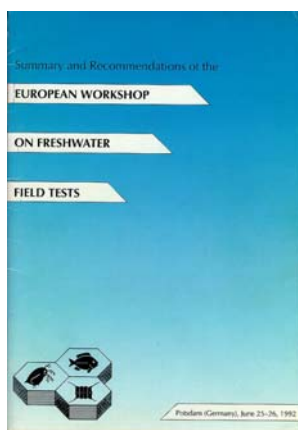


## Further single species tests

- Major source of uncertainty is sensitivity of standard species
- Testing further species can reduce this – may be appropriate to reduce TER trigger by up to 10 times
- Recommended number: 5 for fish, 8 for invertebrates
- Species Sensitivity Distributions



## Cosm guidance – early 1990s



### Workshop on Aquatic Microcosms for Ecological Assessment of Pesticides



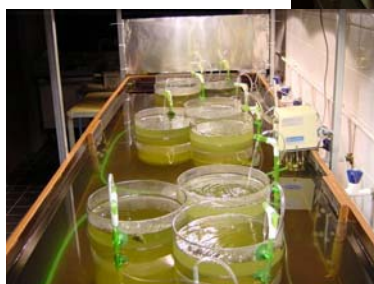
Sponsored by:  
The SETAC Foundation for Environmental Education  
and  
RESOLVE (a program of the World Wildlife Fund)



## Indoor multi-species tests

- Simple – several species
- Semi-realistic – natural assemblages

Alterra, Wageningen, The Netherlands



## Semi-field studies

- Microcosms and mesocosms
- EU guidance on conduct and interpretation of studies



## New approaches with meso- and microcosms

- Studies more focused on concerns identified in lower tiers
- Variety of systems possible depending on objective
- Recommendations on appropriate methods
- "Things should be made as simple as possible, but not any simpler" Einstein

