

Registration Procedure of Plant Protection Products in Europe

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(thanks to Theo Brock,, Steve Maund and Paulien Adriaanse)
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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

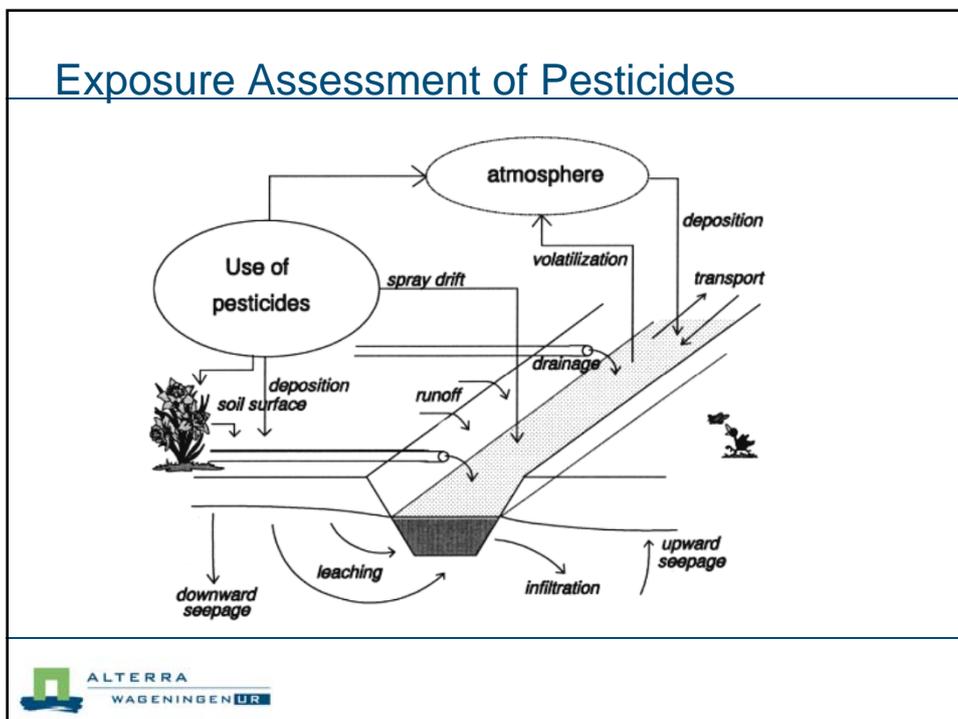
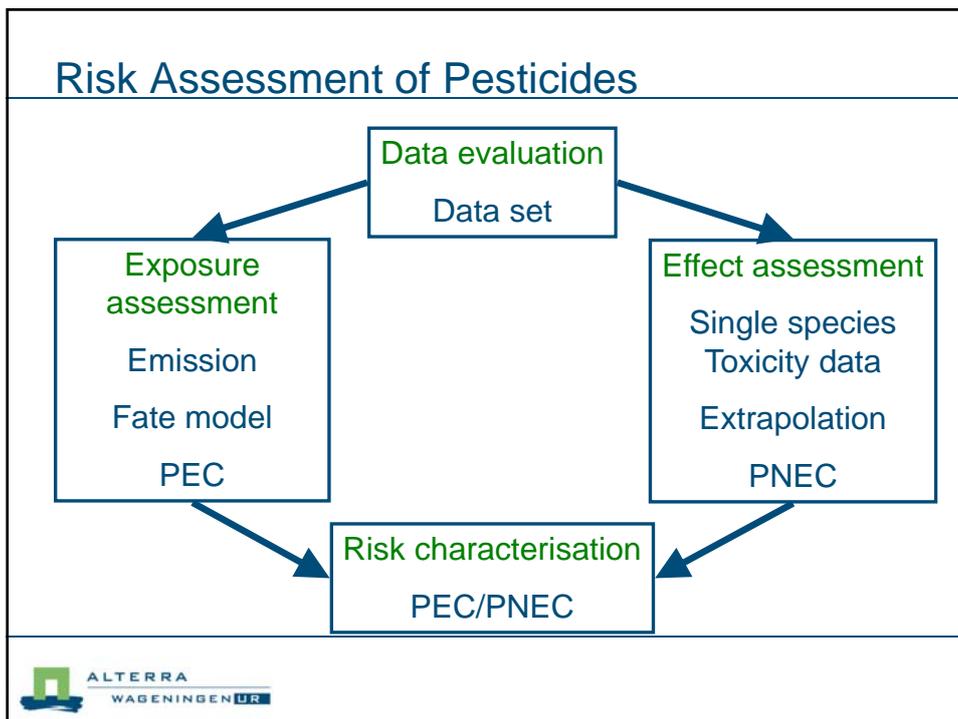


Risk Assessment of Pesticides

Legal Framework

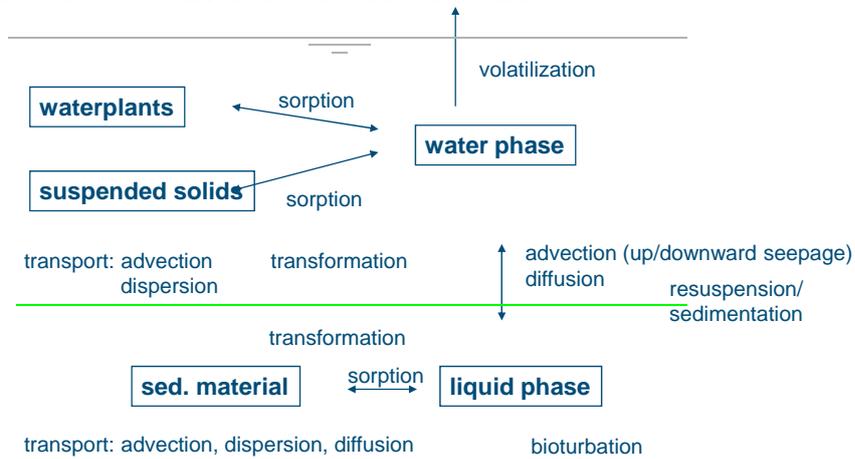
- Industry provides required data
- One of the regulatory bodies performs risk assessment at the EU level
- After registration in EU, registration for (groups of) individual countries can be requested





Exposure Assessment of Pesticides

Processes in water and sediment



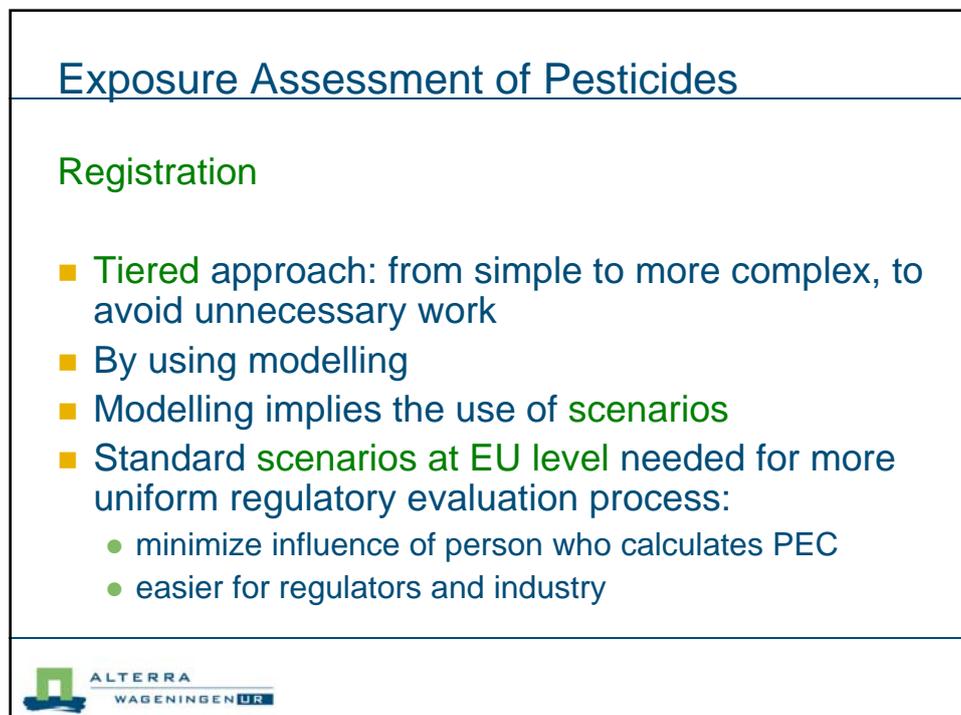
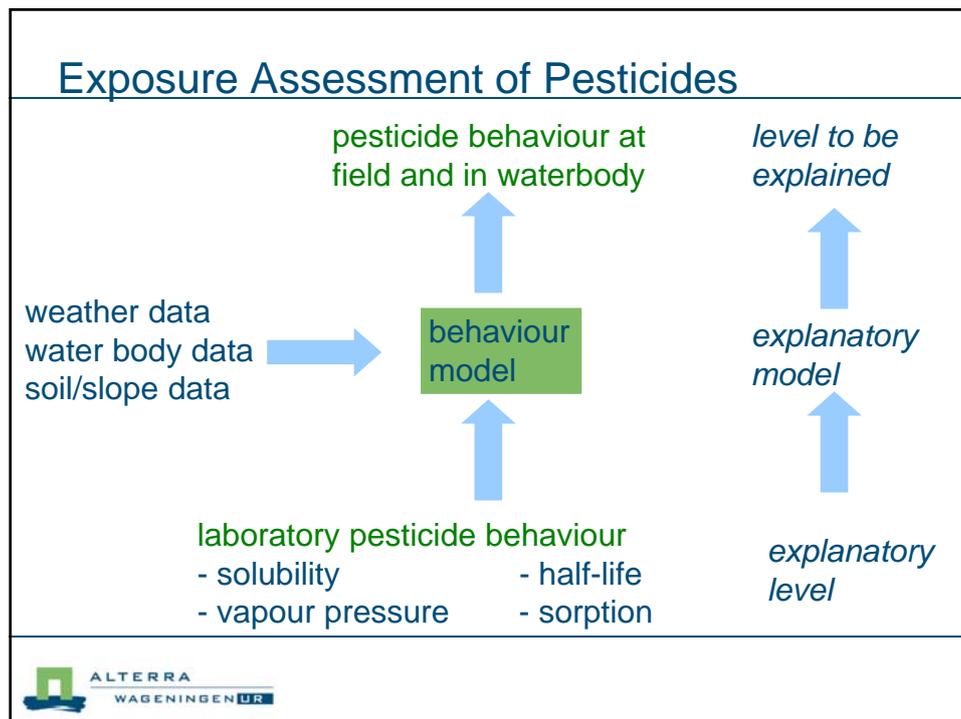
Exposure Assessment of Pesticides

■ Problems:

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

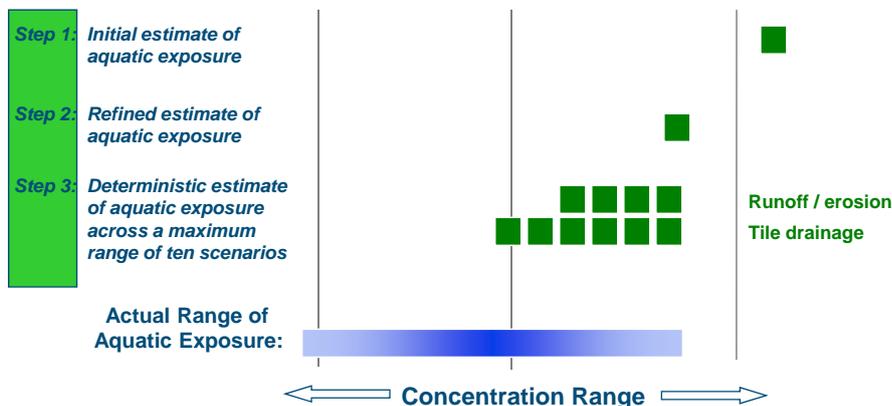
■ Modelling:

- 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

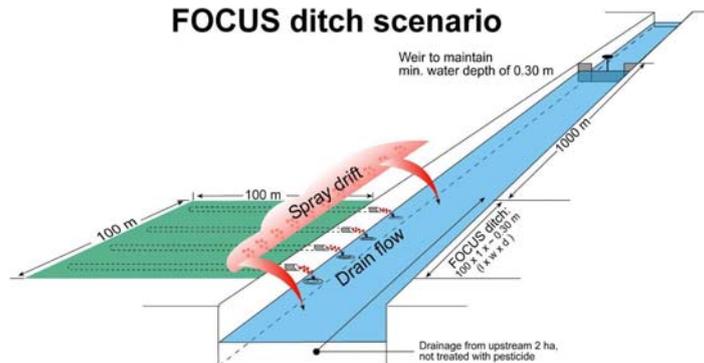
Step 3: scenario definition

- 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

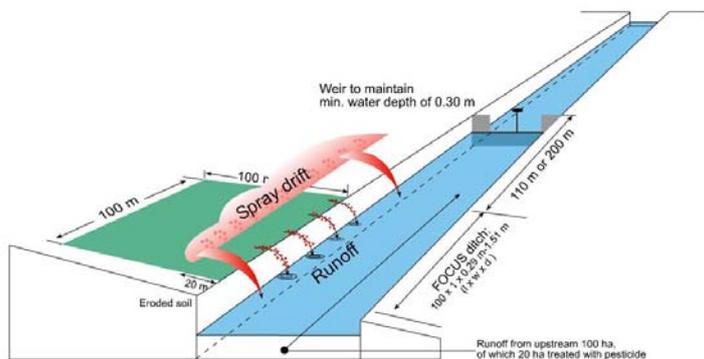
FOCUS ditch scenario



Exposure Assessment of Pesticides

■ Scenarios

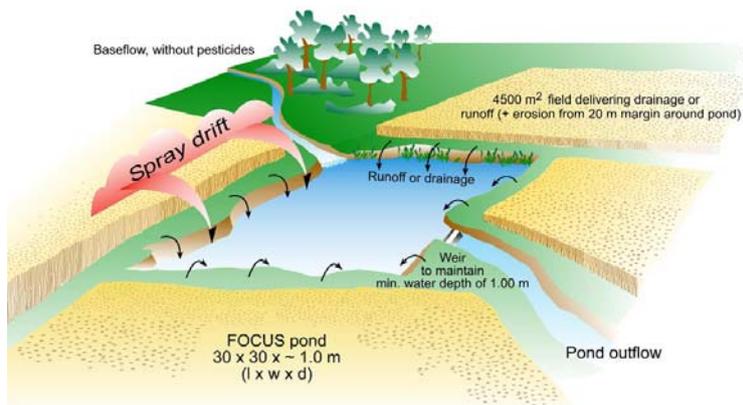
FOCUS stream scenario



Exposure Assessment of Pesticides

■ Scenarios

FOCUS pond scenario



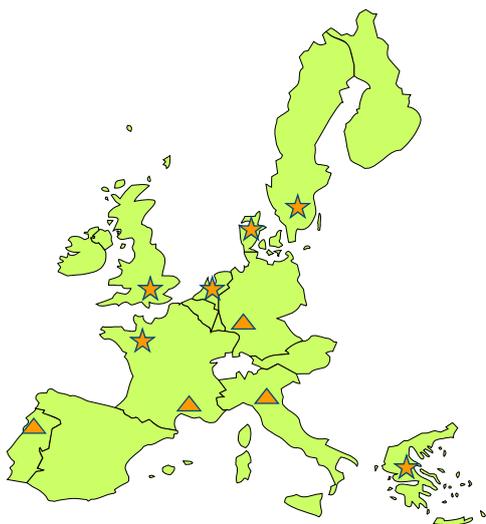
Exposure Assessment of Pesticides

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:

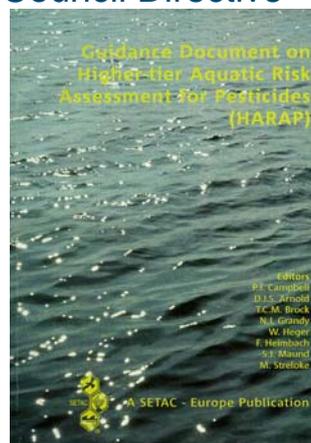
- Possible risk refinement steps:
 - site-specific modelling (entries, characteristics water)
 - more rigorous probabilistic modelling
 - landscape modelling (e.g. GIS for distance crop-water)
 - field studies, higher-tier ecotox studies
- Possible mitigation steps:
 - reduction of spray drift (e.g.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



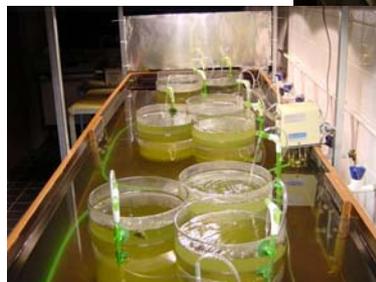
Cosm guidance – early 1990s



Indoor multi-species tests

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

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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

