

# Dutch Registration Procedure for Plant Protection Products and criteria for water organisms

## Development of guidance in accordance with 91/414 and WFD

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# Outline presentation



## Problem formulation

- Different aims of Water Framework Directive (WFD) and 91/414/EEC
- EU policy on the relationship between WFD and 91/414/EEC
- “Special needs” for combining these regulations in the Netherlands

## Dutch policy model (risks for aquatic organisms)

- Spatial differentiation to combine both regulations
- Pre-registration exposure and effects assessment
- Post-registration feedback with monitoring data



# Comparison 91/414/EEC and WFD



## 91/414/EEC

- Prospective risk assessment approach for PPPs
- Based on GAP
- Standard test methods (*GLP*)
- Tiered approach (*e.g. SSD's, micro/mesocosms, models*)
- SSD based on tox data sensitive taxonomic group
- Recovery of effects may be considered (*NOEAEC*)

## WFD

- Retrospective hazard assessment all chemicals
- Not restricted to GAP
- Mining of literature data
- Weight of evidence (*focus on SSDs, considering cosms*)
- Specific toxic mode-of-action initially not considered
- Population recovery not considered in EQS setting

Differences may lead to different acceptable concentrations

# Case: fungicide captan

	<b>Short-term (µg/L)</b>	<b>Long-term (µg/L)</b>
WFD-standard	0.34 (lowest LC50/100; Salvelinus fontinalis)	0.34 (lowest NOEC/50; <i>Pimephales promelas</i> )
91/414 Regulatory Acceptable Concentration (RAC)	31.1 (SSD approach fish; HC5 based on LC10s)	1.7 (lowest NOEC/10; <i>Pimephales promelas</i> )
<b>91/414 : WFD ratio</b>	<b>91</b>	<b>5</b>
Chemical monitoring in larger water bodies	Highest peak < 0.1 µg/L	
PEC (Toxswa) in drainage ditch	30.2 µg/L (peak)	

# EU policy on the relationship between WFD and 91/414

- The European commission was requested by Member States to harmonize WFD and 91/414
- Both the Commission and the Council agree that Member States should tackle this policy gap on the National scale
- The Netherlands decided to develop a new policy model for the registration procedure of PPPs, based on both WFD and 91/414 requirements
  - Finding support in EU important for NL



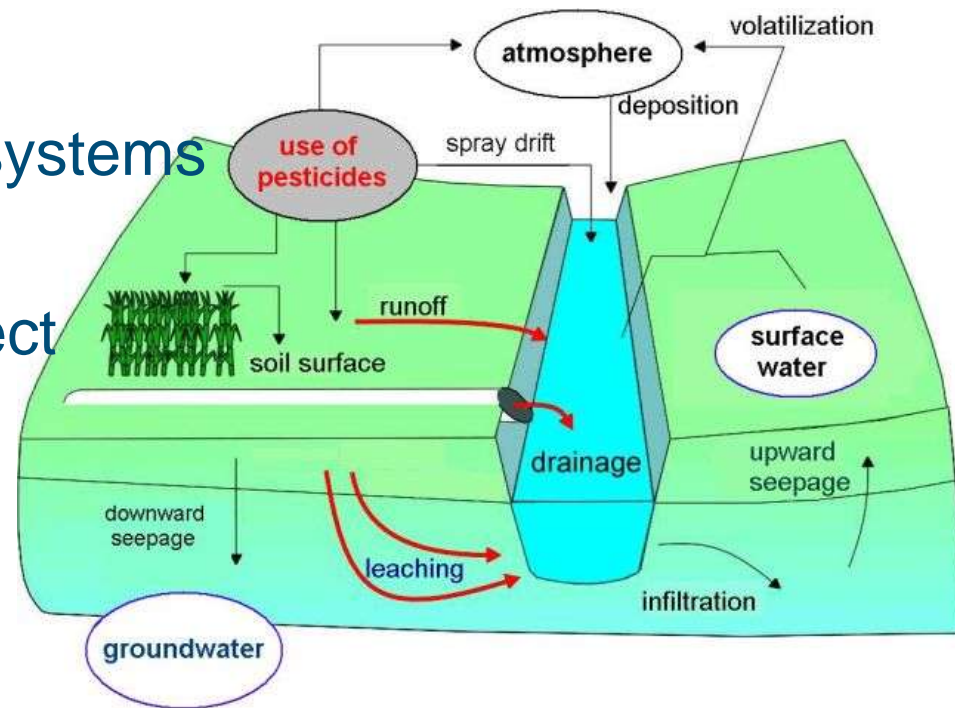
Stricter criteria for water organisms in new PPP regulation do not fully solve the problem

# “Special need” for combining regulations WFD and 91/414 in NL

- Netherlands situated in a delta area of the rivers Rhine, Scheldt, Ems and Meuse
- Dense surface water network, with a relatively low rate of flow
- High agricultural activity

## Therefore

- Vulnerability of Dutch water systems in terms of PPP emissions
- Agricultural activity in the direct vicinity of surface waters





# Dense surface water network in Dutch

polders



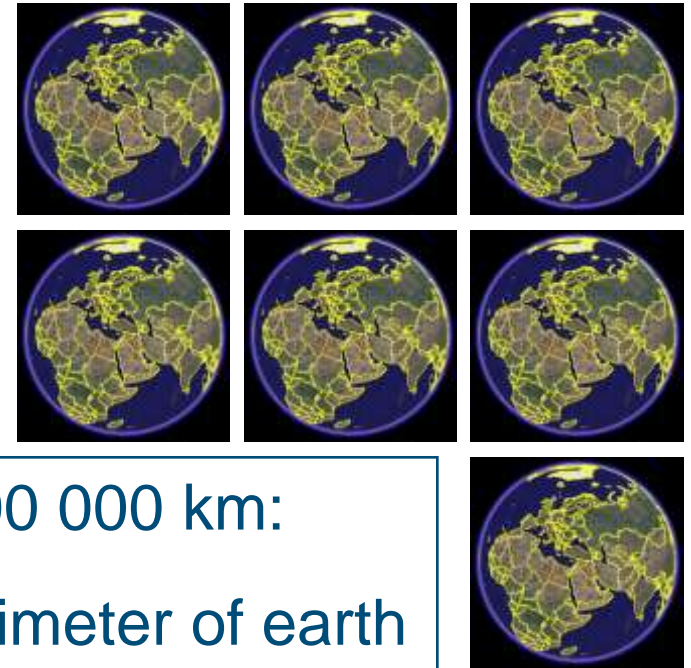
Risk mitigation measures by adopting wide buffer strips not realistic

# Quantitative data on drainage ditches in NL

91 000 km small, temporarily dry ditches

159 000 km ditches < 3 m

56 000 km ditches > 3 m



In the Netherlands ditches are interconnected with other types of freshwater ecosystems (e.g. streams, lakes, rivers)



# Dutch policy model (risks aquatic organisms)

## Prospective pre-registration exposure and effects assessment:

Two connected spatial targets (domains) in the water system;  
the most stringent is leading for PPP-registration!

- **91/414/EEC domain**

**Edge-of-field ditches** in compliance with tiered risk assessment approach

- **WFD domain**

**Larger water bodies** in compliance with water quality standards (similar to AA-EQS and MAC-EQS)

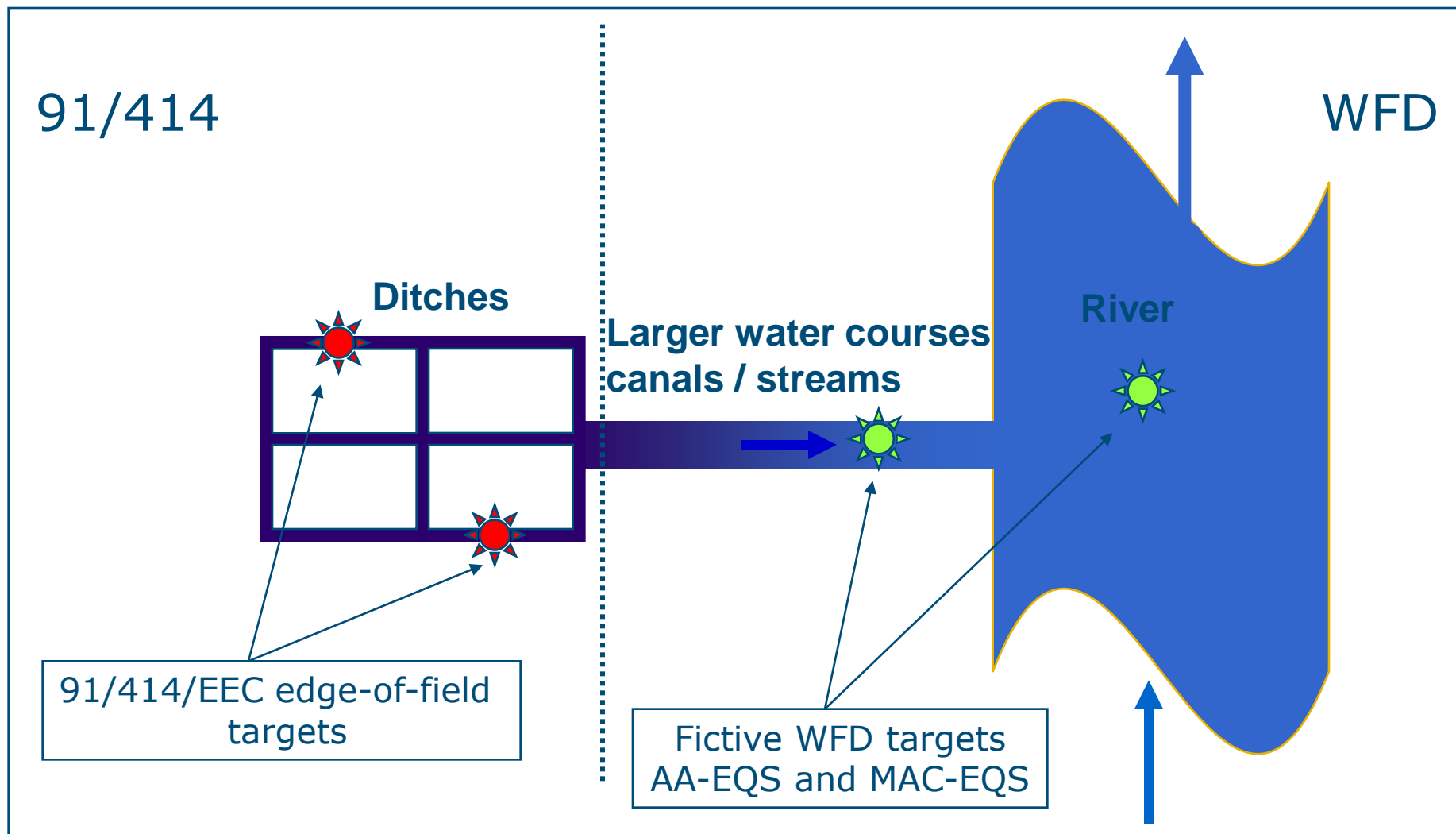
Indirect pressures as a result of edge-of-field exposure (CASCADE: landscape-level exposure model)

## Retrospective registration measures:

**Feedback mechanism based on (WFD) monitoring data**

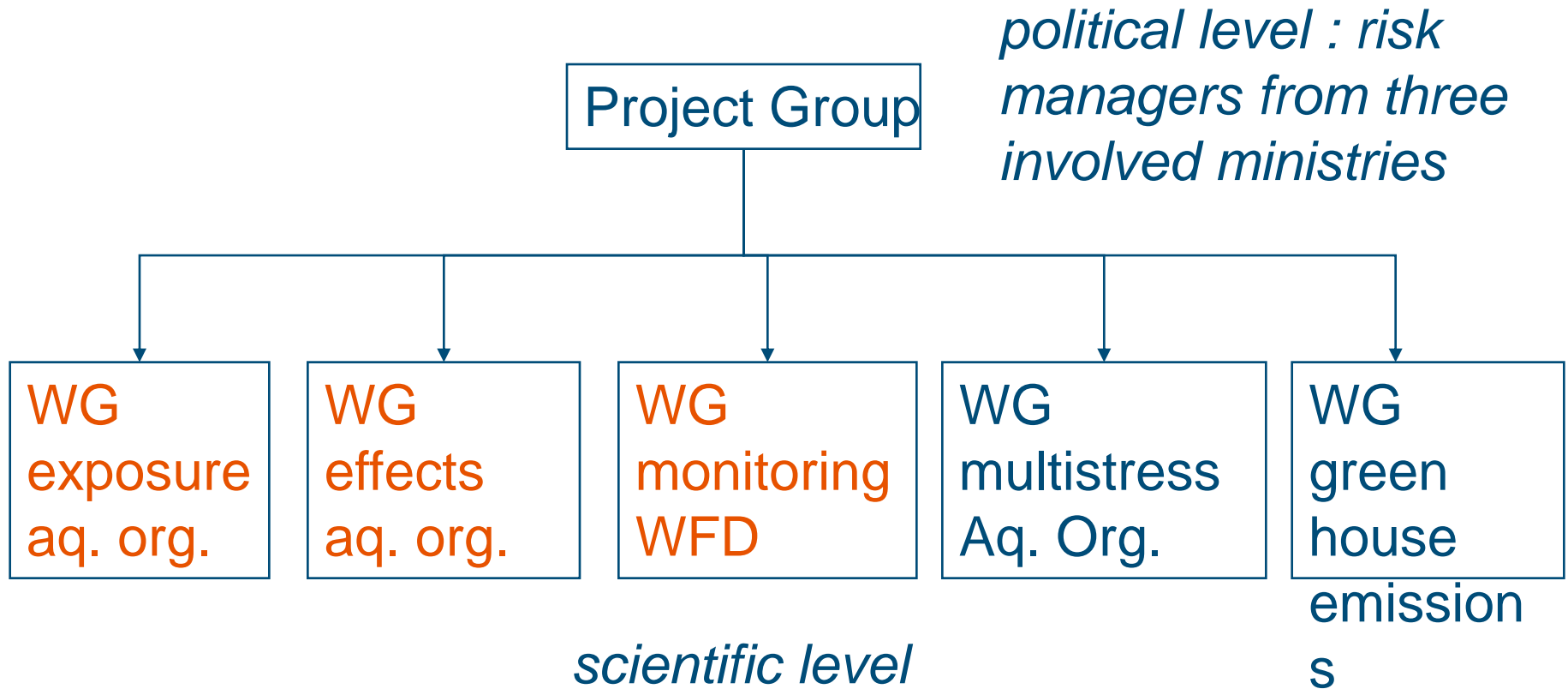
Exceedance of EQS leads to additional research and/or measures and may ultimately end the registration

# Spatial component (scenario approach)



Aim: Spatial differentiation in compliance to different EU regulations

# Organisation structure project



Five parallel workgroups with interaction where necessary (e.g. linking of exposure and effects)

# Prospective exposure modelling

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Exposure scenarios and models for two types of interconnected surface water:

- Edge-of-field ditches
- WFD water bodies



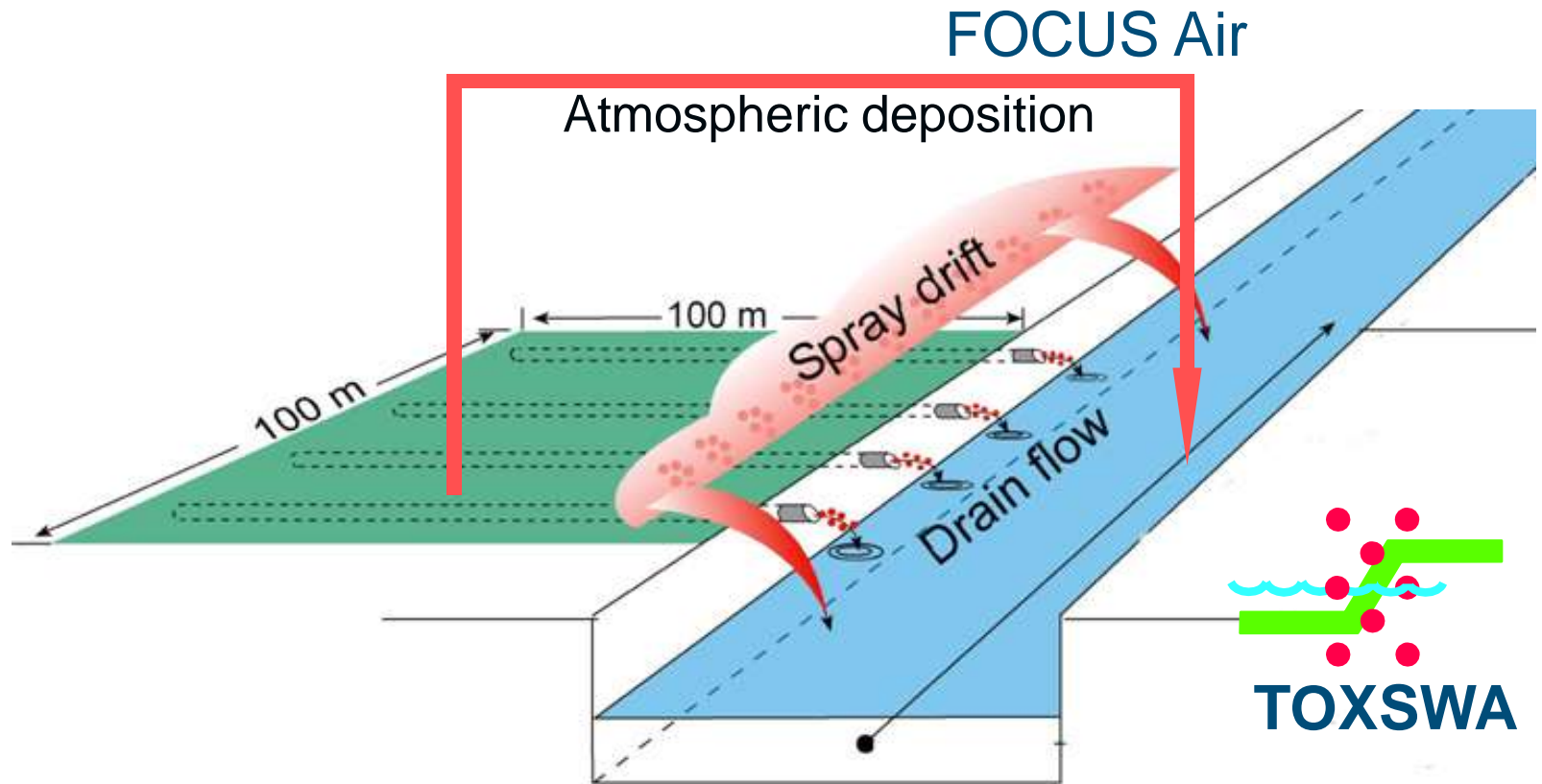
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Based on expected agricultural use of the PPP



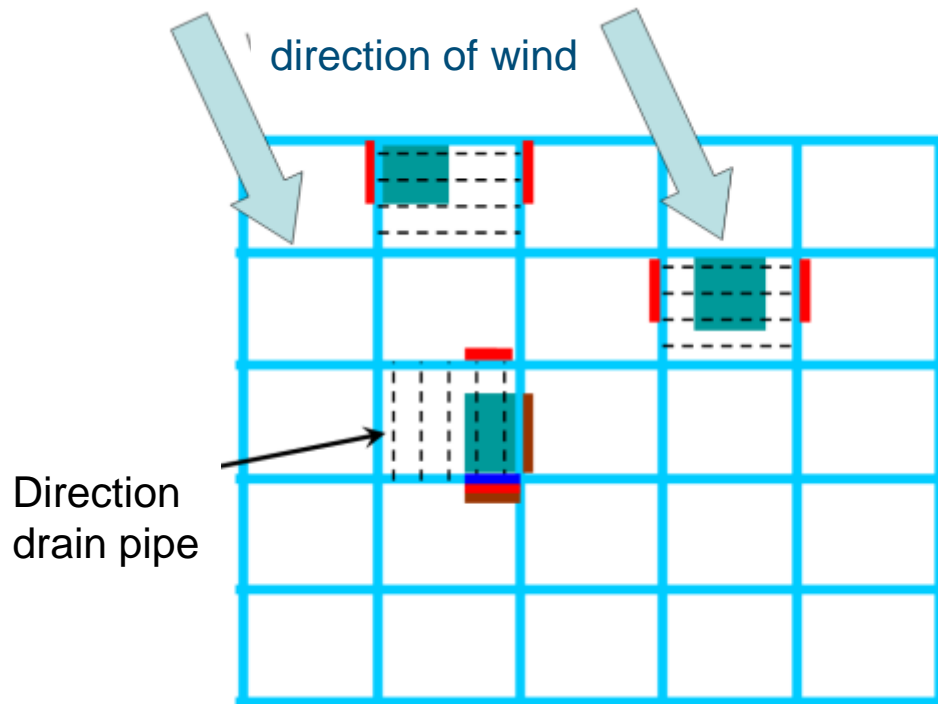
# Edge-of-field exposure modelling

## Conceptual model of scenario



# Exposure modelling & risk management decisions

- **Edge-of-field:** 90<sup>th</sup> percentile exposure concentration of a selected population of drainage ditches

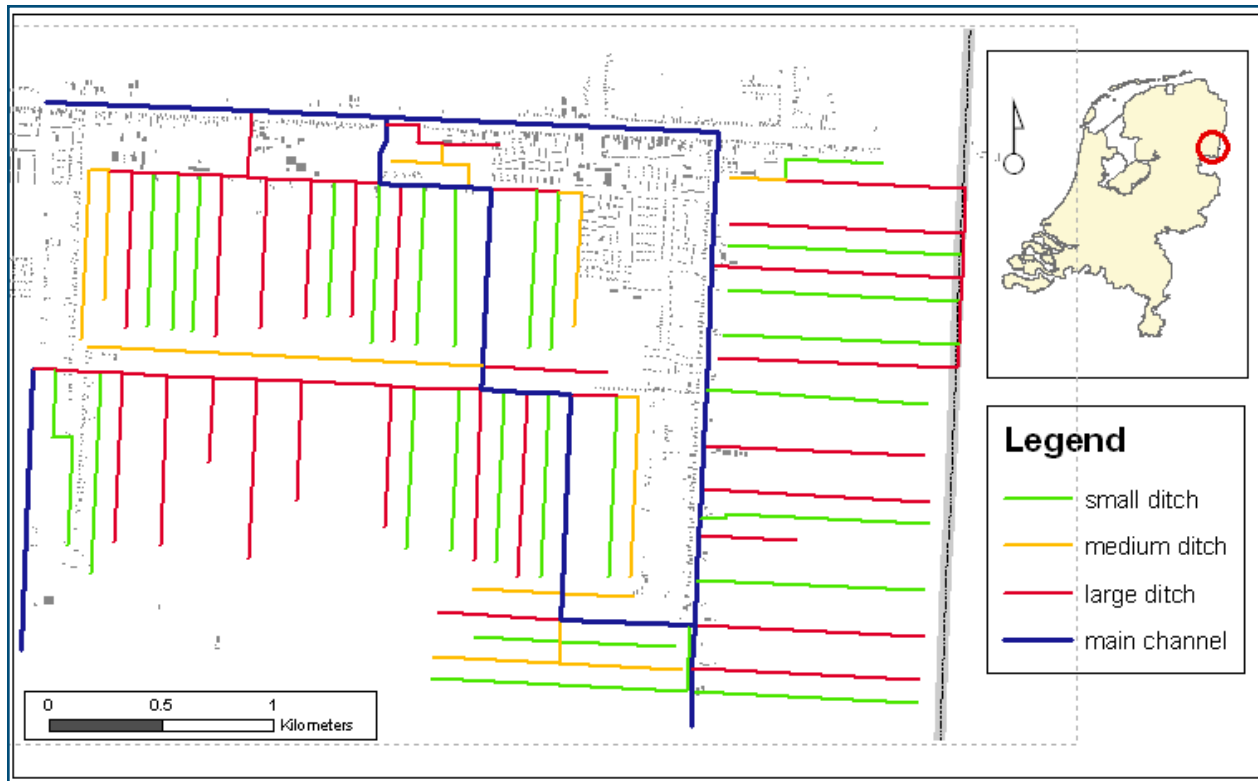
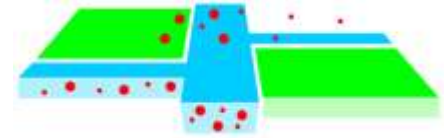


Ditches that are located downwind of treated fields AND that have drain pipes from treated fields

- included
- excluded
- drift
- drain-pipe

# Exposure modelling for WFD water bodies

CASCADE model: behaviour of pesticides in system of water courses at scale of 10 km<sup>2</sup>



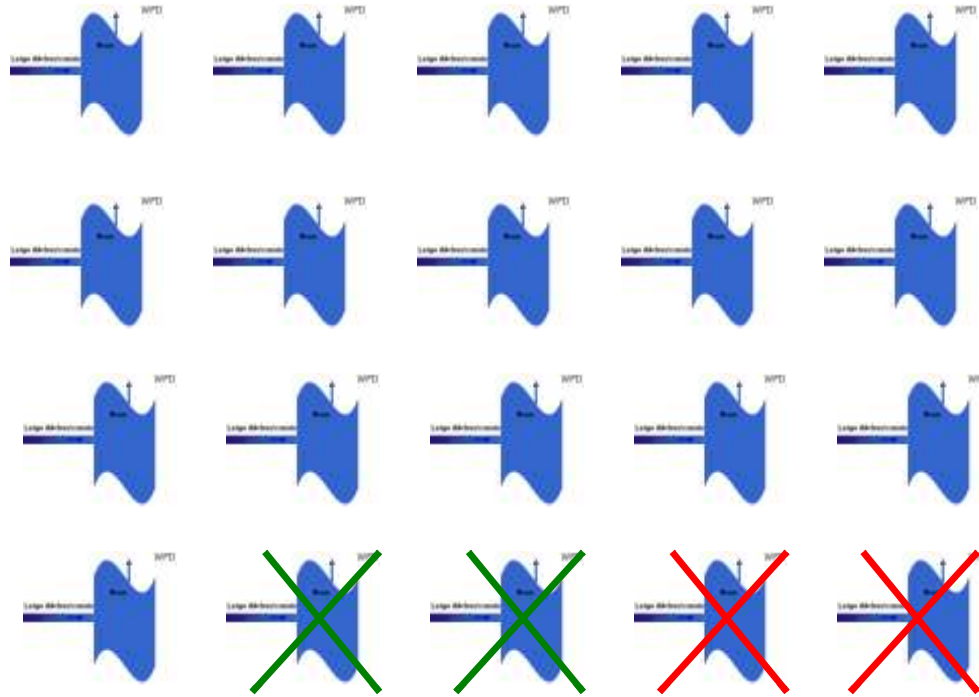
First system of ditches parameterised in CASCADE

Different realistic landscape-level scenarios have to be developed

The CASCADE model is under development

# Exposure modelling & risk management aspects

## WFD water bodies: Some open questions



The higher the percentile the higher the predicted exposure concentration

Which spatial percentile to select within an individual water body and for the total population of relevant water bodies (e.g. 80, 90 100%)?

What are the relevant WFD water bodies to take into account (e.g. only freshwater systems of agricultural landscapes)?



# Prospective effects assessment

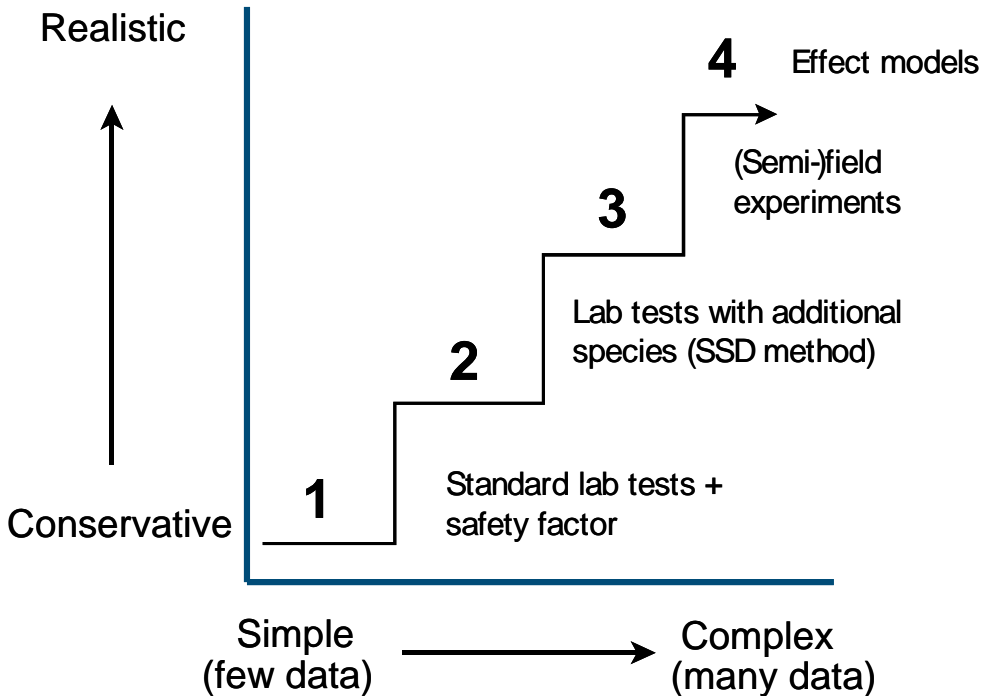
Decision trees for ecotoxicological effects in two types of interconnected surface water:

- Edge-of-field ditches
  - Ready end 2009
  
- WFD water bodies
  - Ready end 2010



Based on single-species toxicity tests, semi-field studies and extrapolation models

# Edge-of-field effects assessment (91/414)



Tiered approach and linking exposure to effects according to ELINK recommendations

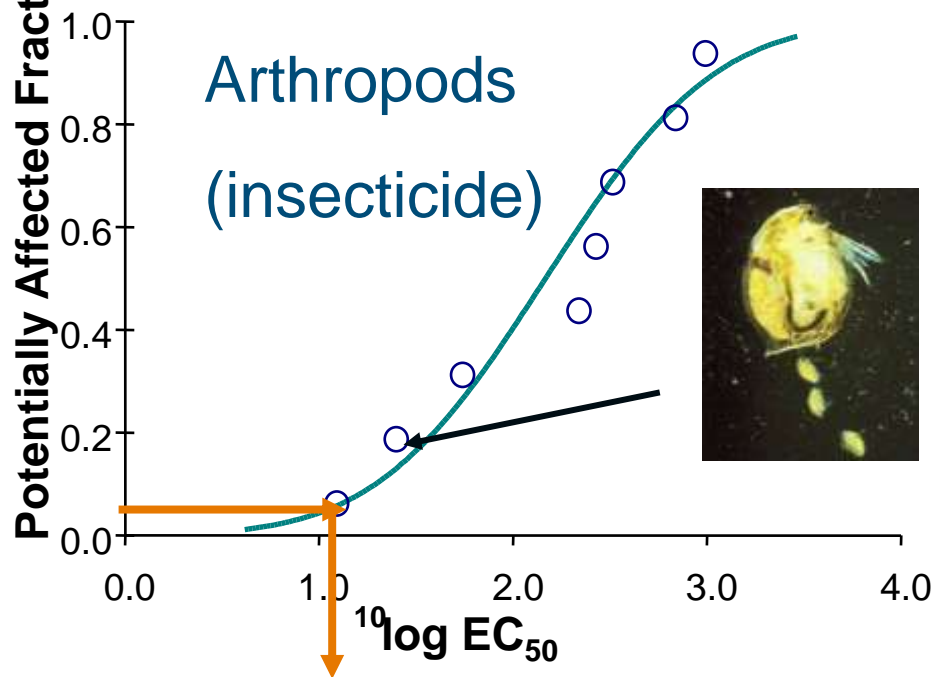
## Issues to solve

- Higher-tier chronic studies are scarce
  - Is first tier protective?
  - Spatio-temporal extrapolation of chronic higher-tier studies
- Is ecological recovery realistic to consider when more PPPs are used?

Aim is to follow as much as possible the Guidance Document on Aquatic Ecotoxicology (currently updated by EFSA)

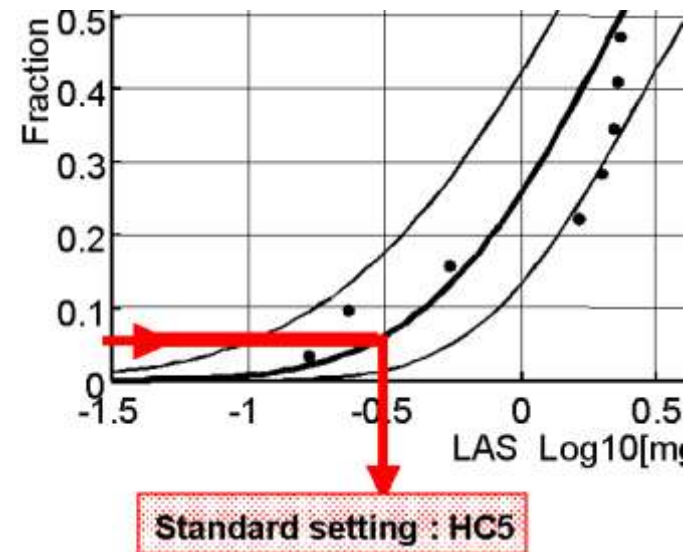
# Edge-of-field effects assessment (SSD approach)

## Species Sensitivity Distribution (SSD)



Minimum dataset: 8 tox data of **representative sensitive taxomical groups** (5 for fish)

Most experience with acute SSDs



RAC = median acute HC5/3, lower limit acute HC5, or median acute HC1 for repeated pulse exposures (Maltby et al 2009)

# Edge-of-field effects assessment



- Well-performed micro/mesocosm studies may be used to derive a  $\text{NOEC}_{\text{community}}$  or a  $\text{NOEAEC}$  (considering recovery)
- To derive a RAC from a  $\text{NOEAEC}$  (e.g. Effect class 3a) an AF of 3 may be necessary
- Micro/mesocosm experiment with potted plants are a higher-tier option for macrophytes

Limited experience with long-term chronic exposure regimes



## Prospective effects assessment for WFD water

bodies

- First tier effects assessment as required in the new draft PPP regulation not in conflict with WFD

### Issues to solve

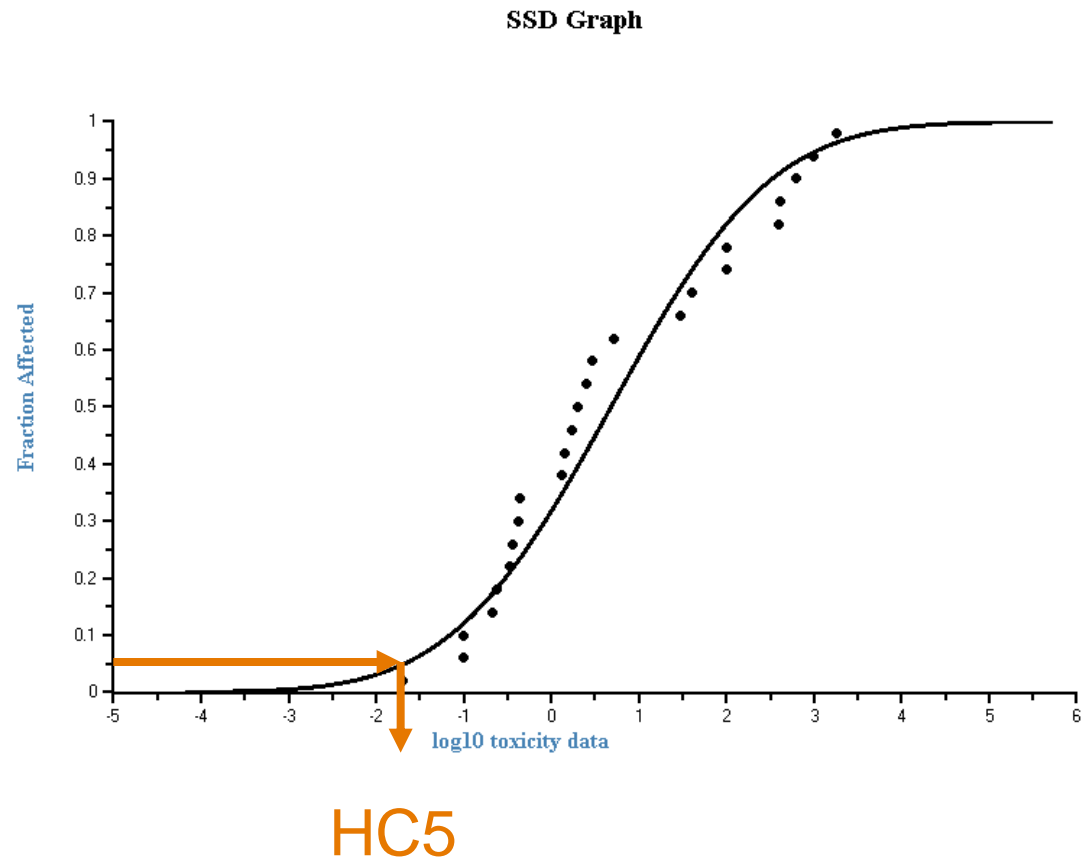
- The specific toxic-mode-of-action of PPPs and the selection of toxicity data to construct the SSD
- Scientific underpinning of the height of the AF used to extrapolate HC5 values of SSDs and  $\text{NOEC}_{\text{community}}$  values of micro/mesocosm studies
- Linking of Water Quality Standards to PECs (What should be the time-window of the long-term PEC ?)

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Aim is to follow as much as possible the Technical Guidance for Deriving Environmental Quality Standards (currently updated)

# WFD: SSD approach

- Minimum dataset:  
10 tox data of 8  
different taxonomic  
groups (usually not  
available)
- Chronic data for AA-  
EQS
- Acute data for MAC
- AF of 1-5 to chronic  
HC5 to derive AA-EQS
- AF of 10 to acute HC5  
to derive MAC



To avoid excessive animal testing criteria are needed on which tox data to use if the PPP has a specific toxic-mode-of-action

# Post-registration chemical monitoring in WFD water bodies

**Chemical monitoring indicates potential problem (Conc. > EQS)**

## **Evaluation of possible reasons for exceeding the standards using the plausibility protocol**

- Check for unexpected emission routes (adopt to pre-registration model)
- Check pre-registration model for necessary parameter updates
- Compliance check for GAP (Emissions not related to agricultural use?)
- Check the possibility of illegal use

## **Actions (preferable undertaken by industry; product stewardship)**

- Emission limiting measures (check with new monitoring data)
- Ultimately end of registration (authority CTGB)

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Chemical monitoring in ditches may be required if registration is based on a RAC that takes into account ecological recovery

# Thank you for your attention

## Questions ?

