

Link between monitoring and modelling –

Dealing with groundwater monitoring in the GW tiered risk assessment

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**7th EU Modelling Workshop
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Resolutions from 2012 ...

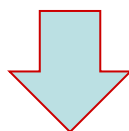
- Need to better understand the link between GW + SW monitoring
- Consensus reached in the EU scientific regulatory community should be used in the EU risk as soon as possible

OUTLINE

- Link between monitoring and modelling
 - Context: is there a link ? (in general, specific)
 - Monitoring in regulatory context
 - Monitoring : « Interpretation keys »
- Dealing with groundwater monitoring in the GW tiered risk assessment (example)
- Using monitoring data : What is a needed
- Ongoing actions

Context: is there a link ?

**Modelling
(Ground/Surface Water)**



**Regulatory risk
assessment**



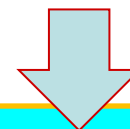
**Plant Protection
Product directive
(1107/2011)
“PPP registration”**

**Monitoring (public)
(GW/SW)**



**National dataset
(public information)

“Water suppliers”**



**Water Framework
Directive
(2000/60/EC)
“drinking water”**

link ? Common point

**Modelling
(Ground/Surface Water)**

**Regulatory risk
assessment**

**Monitoring
(GW/SW)**

**National dataset
(public information)
+
“Water suppliers”**

On both sides practices can be very “Extreme”

**12 steps of PECgw calculation
refinements???**

**“It may not help the regulatory
process but models can do it”**

...

“and there is no guidance”

**10.000 analysis of this
“fungicide B” not ever been
used around ?**

**“The laboratory has the
analytical methods to do it”**

...

is there a link ?

**Modelling
(GW/SW)**

**Monitoring
(GW/SW)**

In general, most of the monitoring « public » data are :

- Not generated for regulatory risk assessment purpose**
- Not generated in order to produce systematic feedbacks on regulatory risk assessment**

link ? Common point:

**Modelling
(GW/SW)**

**Monitoring
(GW/SW)**

– For the risk manager (EU commission) :

Both can be confirmatory information

Confirmatory data

Modelling
(GW/SW)

Example 2013:

-The applicant shall submit confirmatory information as regards :

(1) the risk to groundwater from the active substance and its metabolites

During the EU process impossible to derive PEC_{gw} for the AS; Resolutions ?

Confirmatory data

Monitoring
(GW/SW)

Example “2013”

“Conditions of authorization shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from the metabolites A, B, C in vulnerable zones, where appropriate.

+ submission of further information on the relevance of the metabolites

-
- Consensus reached in the EU scientific regulatory community should be used in the EU risk as soon as possible

“Needed ?” / “Urgent ?” / Already late?

– **Risk managers are including monitoring in regulatory process**

– **+ social demand**

link ? Both deal with 'some Reality'

**Modelling
(GW/SW)**

**Monitoring
(GW/SW)**

**Mimic the Reality
(processes/spatial data)**

"Reality"

**Herbicide used on
cereals**

**Herbicides used on
cereal + Non
agricultural +
biocide ...**

link ? Yes, in FOCUS

Tier 1)
Standard FOCUS scenarios with lab. or field degradation studies

zRMS to integrate or not the higher tier (> tier 1)

Tier 2a)
Modelling with refined parameters

Tier 2b)
Modelling with refined scenarios

Tier 3a)
Combined modelling
refined parameters and
scenarios

Tier 3b)
Advanced spatial
modelling

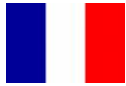
Tier 3c)
Higher tier leaching
experiments set into context
by modelling

Tier 3d)
Other modelling
approaches

Tier 4)
Groundwater monitoring

Monitoring in regulatory risk assessment

Regulatory zones



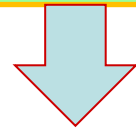
Re-examination of preparation (after Annex I Renewal)



Monitoring (public data set) (GW/SW)



Re-examination of Active Substance (AIRIII)



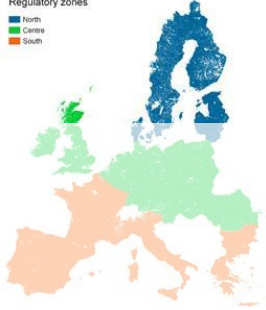
Literature review (can include Monitoring if “peer review”)

Monitoring in regulatory

Regulatory risk assessment

Regulatory zones

North
Centre
South



Re-examination of preparation (after Annex I Renewal)



Monitoring (public data set) (GW/SW)



Specific monitoring



Re-examination of Active Substance (AIRIII)



Literature review (can include Monitoring)



Specific monitoring

Specific monitoring

« Dedicated » monitoring studies conducted by industry for regulatory purpose :

- Requested by member state**
- “Voluntary” targeted monitoring studies performed by industry**

Monitoring in regulatory

What is available?

Specific monitoring

**Public
database**

**Focus on a
particular
compound**

**Industry specific
monitoring**

**-Identification of wells
(with detections)
-Area of use (pressure)**

**-Pressure of use
-vulnerability
-best descriptor**

Interpretation keys (frequency/sampling date...)

Active substance (few metabolites)

AS+metabolites

Monitoring : Interpretation keys

Pressure of use on the
area(s)
(where the product is used)
“industry”

Vulnerability of
the area(s)
(transfer time)
“Hydrogeologist”

Pressure

**Risk
assessment**

Vulnerability

**Aim: Risk managers to take decision
+Mitigation measures**

Interpretation keys / guidance : what do we have?



**No guidance document
(some recommendations in Efsa opinion)**

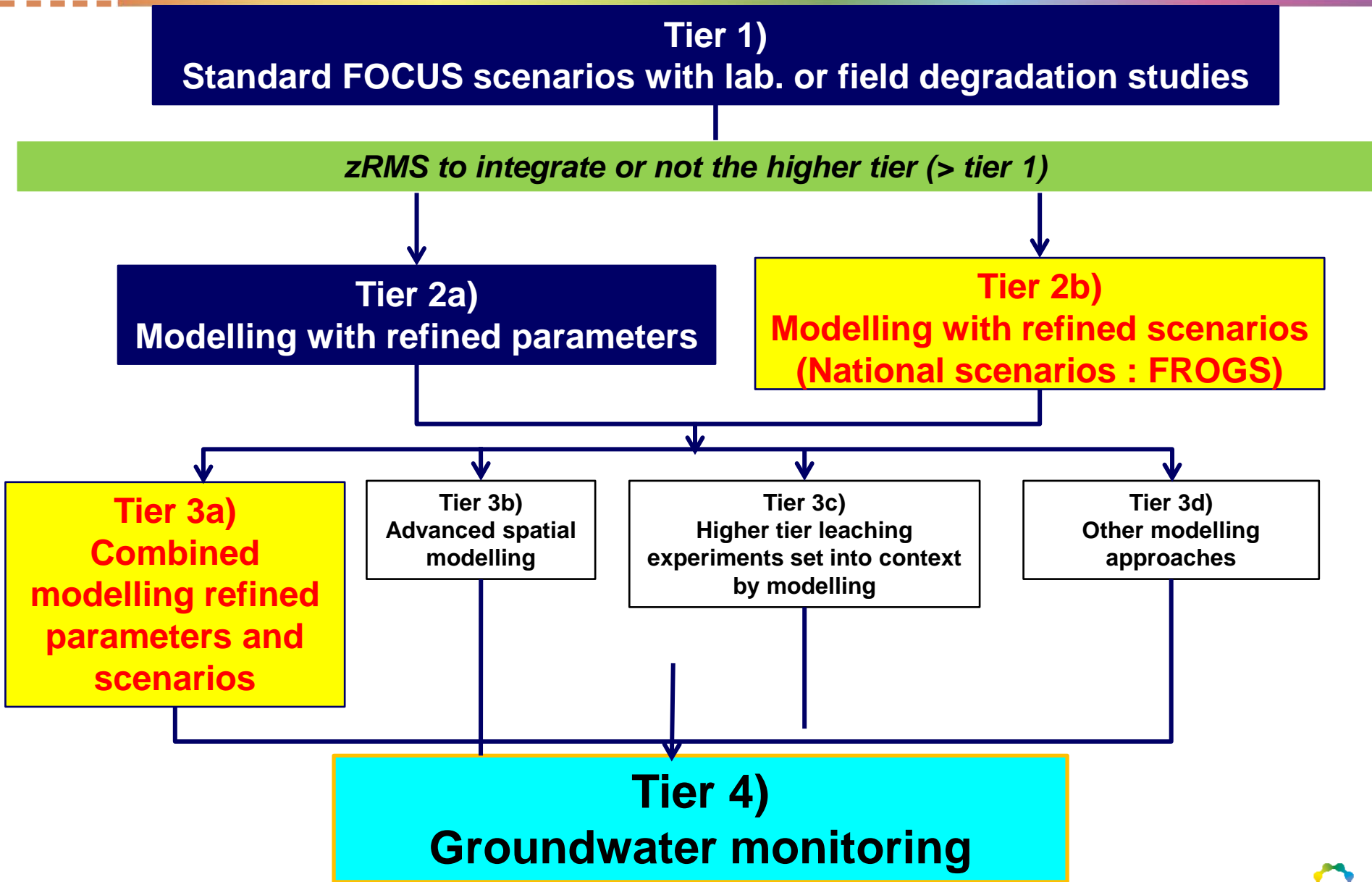
Regulatory zones



**National guidance exist (UK, NL, GER);
are updated ; or ongoing**

Feedback on previous experiences (FR)

Example : Case of the active substance B (Tier 1 to 4)



Example : Case of the active substance B (Tier 1 to 4)

Uses : Sugar Beet; 1200 g/ha; Treatment every third year

**FOCUS modelling
(PEARL v4 + PELMO v4)**

**FROGS modelling
(FROGS v2)**

**Metabolites X
PEC gw >> 10 µg/L**

**Metabolites X
PEC gw >> 10 µg/L**

X1 :
(max. **12 µg/L ; 2 scenarios/6**)

X1:
(14 µg/L)

X2 :
(max. **16 µg/L ; 1 scenario/6**)

X2:
(11 µg/L)

X3 :
(max. **13 µg/L, 1 scenario/6**)

X3,
X4,
X5 <10µg/L

X4,
X5 <10µg/L

X6

X6

National restriction based on both FOCUS and FROGS modellings:

=> no safe use

Example : Case of the active substance B (Tier 1 to 4)

**+Specific monitoring studies performed in FR
(10 representative sites, 40 wells, 8 years).**

To “validate” a monitoring : What is a needed

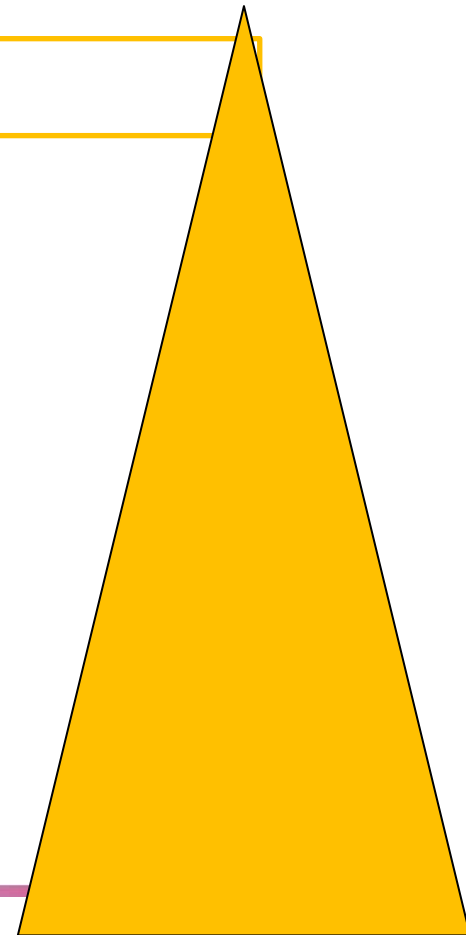
Recommandations: «good monitoring practices»

Sampling site : info on wells

Number/frequency of sampling

Vulnerability / pressure / soil type / P

Data interpretation (max. /mean/ ...)



To “validate” a monitoring : What is a needed

Ongoing actions:

- **Environmental Monitoring Advisory Group on Pesticides (EMAG-Pest), SETAC**
- **Groundwater monitoring sub-group created and work initiated on ‘good monitoring practices’**

Thanks !



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