



Contextualisation of Higher Tier Exposure Studies

Higher tier in Regulatory Risk Assessment

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**9TH EUROPEAN MODELLING WORKSHOP
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Outline

- **Context**
- **Different drivers for conducting higher tiers (“basic drivers” / “good drivers”)**
- **Higher tiers suitable for regulatory purpose** (some considerations)
- **Guidances for regulatory risk assessment** (most recent)
- **Wrap up**

Context

- **Regulatory Risk Assessment is performed using a tiered approach (most of the time)**
- **Higher tiers are frequently (always) included for active substance risk assessment (soil and/or SW and/or GW)**
- **Higher tiers can include refined Risk Assessment (dataset+modelling) + Mitigations measures**

Context : Higher tier exposure

... to do what ?

- PEC_{gw} to demonstrate that the trigger (0.1 µg/L) was not breached (E-fate)
- PEC_{sw} derived to perform aquatic risk assessment (Ecotox)

= No exposure higher tier is performed because the Predicted Environmental Concentrations in Surface Water (PEC_{sw}) is breaching a trigger (i.e. 0.1 µg/L); but because the aquatic risk does not pass.

Exposure X EcoToxicity = Risk

Drivers for producing higher tiers

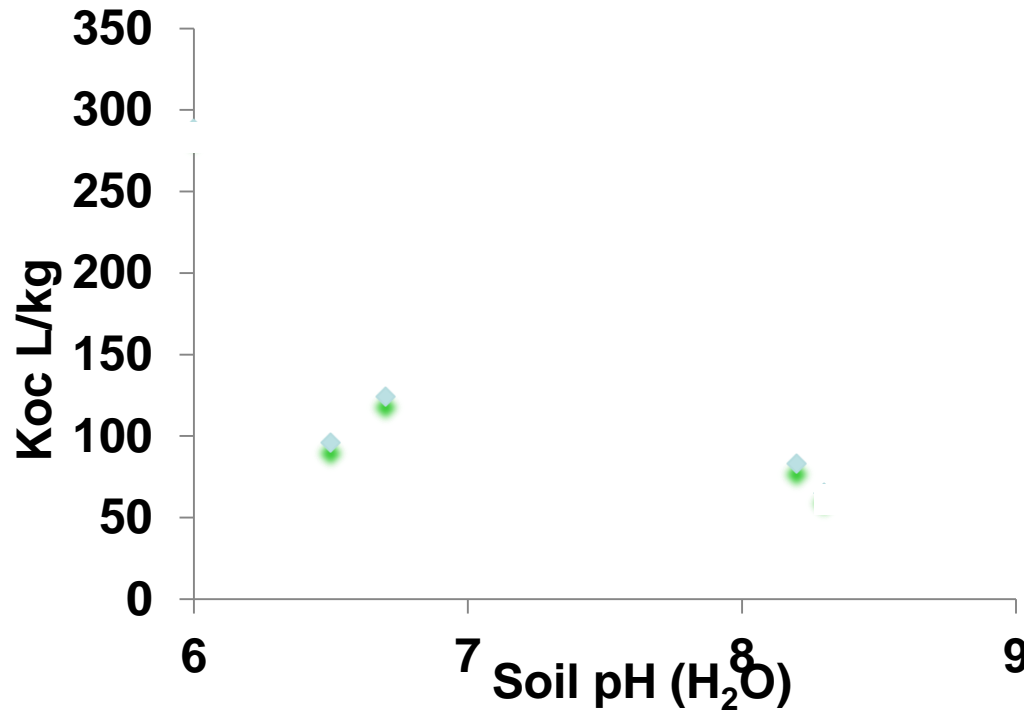
- **Demonstrating no unacceptable risk**
- **New regulatory requirements (minor non transient metabolites)**
- **Handling very specific compounds (inorganic compounds / fumigants)**
- **Reducing mitigations measures**
- **...**

Drivers for producing higher tiers

- Drivers for producing higher tiers can also be more “basic” (i.e. data shortcoming)

- **pH dependency** (when dealing with adsorption/degradation in soil)

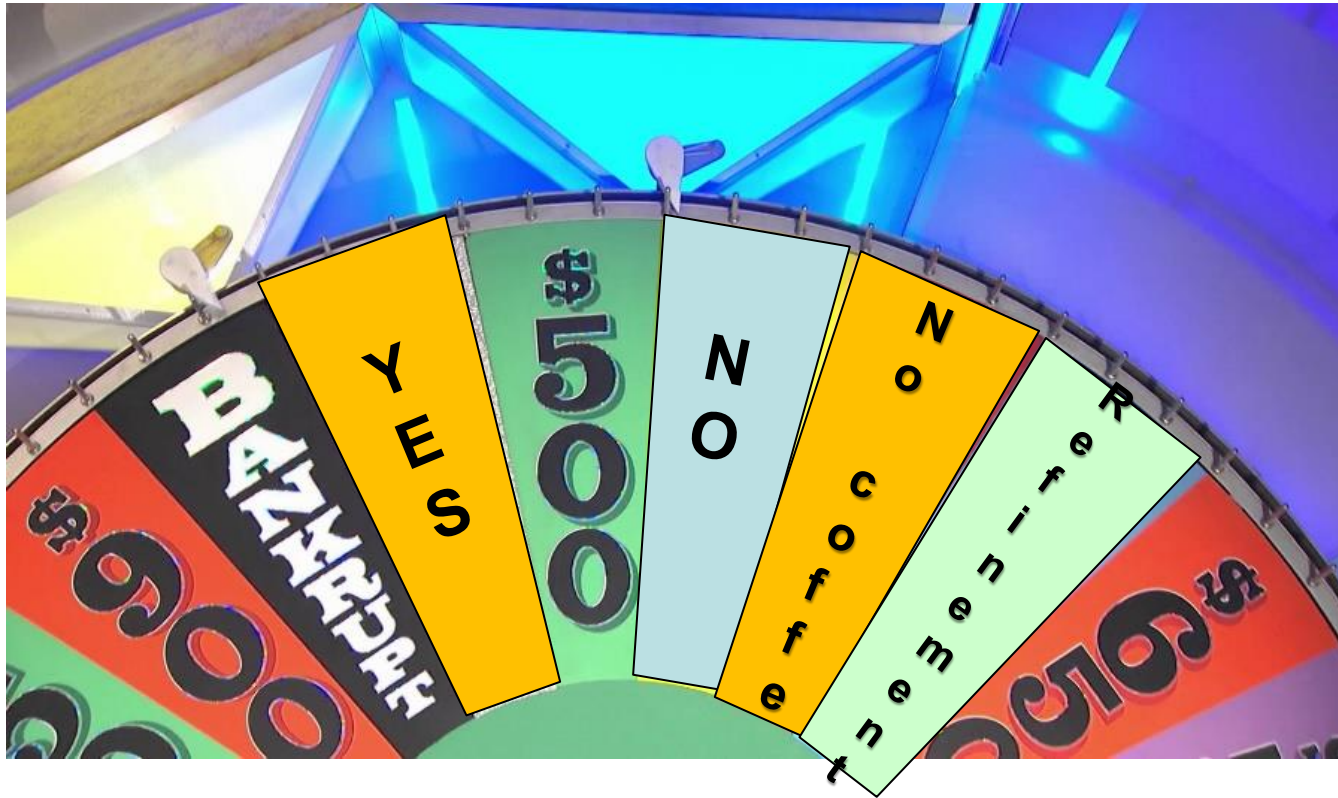
pH dependency



Soil pH dependency : Yes / No / maybe / linear / Kendall test ... with 3 points ...

pH dependency

- Alternative option: pH dependency fortune wheel



pH dependency

Practical case:

pH dependency identify based on few data;
lowest Koc value to be used for conservative GW
risk assessment ...

....inverse modelling/aged sorption/plant uptake
higher tier options proposed as higher tiers...

- Ideally data shortcoming should not be a driver for producing higher tiers (most of the time not efficient)

« True Drivers »: need for higher tier

Groundwater :

- **Trigger breach based on modelling**
- **Monitoring Used as higher Tier**

- **No agreed guidance**
- **Specific approaches**

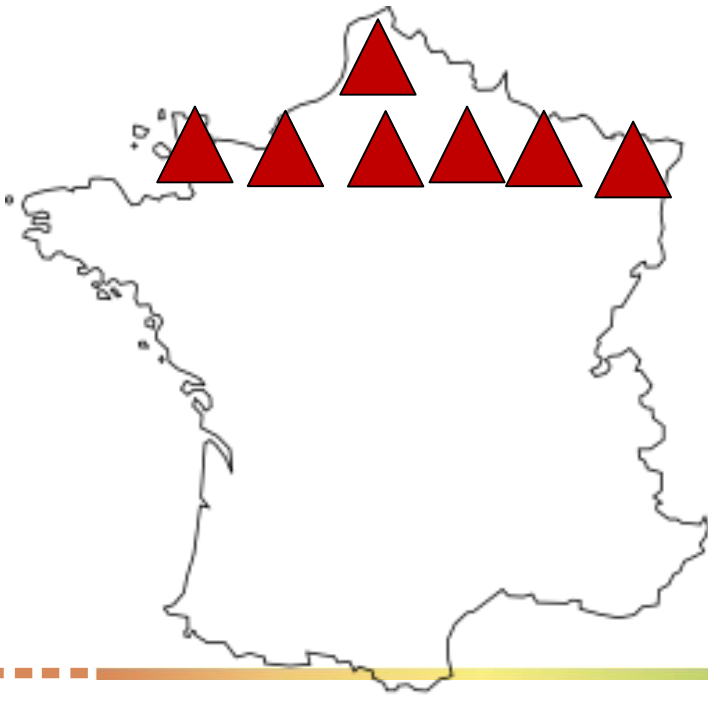
GroundWater Monitoring

- **SETAC EMAG GW : guidance for GW monitoring is not a cookbook (*this was not the intention of the group*) because “It depends” !**

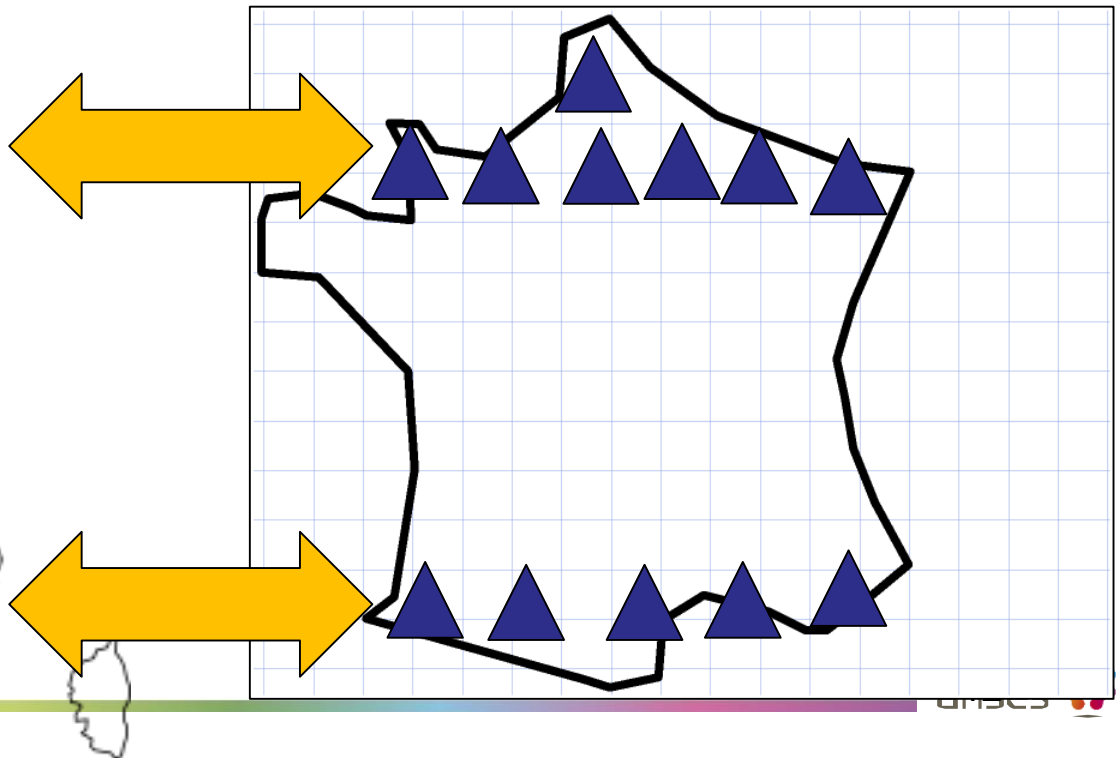
Combining Targeted+Public monitoring (in France)

- Targeted + Public => More accurate picture

Targeted



Public



GW monitoring as Higher Tier

- **Fit with national desires = exchanges are needed**
- **Design can be very specific (and not relevant in other places).**
- **Acceptability based on specific criteria (previous national programs on the same aquifer).**
- **Extrapolation (to other actives) not straightforward**

Why some higher tiers are difficult to handle for regulatory purpose ?

- Because some (all) higher tiers can be really specific (of course)
- Higher tiers are conflicting with harmonization (*for this particular case , with this specific dataset, according to the opinion of some specific expert*),

Higher tiers = Different flavors



Dataset



Higher tier Risk assessment

Harmonization



Higher tier “landscape”

“Science”

“Risk assessment”

“Risk management”

“Good science”

“Suitable for regulatory risk assessment”

Not “good science”

Not “Suitable for regulatory risk assessment”

Need for Harmonisation

Guidances are scientifically based and suitable for regulatory purpose

Guidances in the regulatory risk assessment


Statement:

- **“Regulatory agencies have ‘natural’ aversion against new guidance”**
- **“Regulatory agencies have ‘natural’ liking for new guidance”**

Fate : a constellation of guidances

Guidances in the “Fate” area **Scientific opinion on aged sorption (2018)** **Guidance on soil degradation Kinetic 2 (ongoing)**

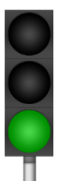
DegT50 guidance 2014 (>may 2015)



Covered crop 2014



PEC soil 2017



Technical report: **OECD 106 evaluators checklist (2017)**

aged sorption (2018)

SETAC EMAG-Pest GW (ongoing)

Guidance on soil degradation Kinetic 2 (ongoing)

SW repair action (ongoing)

Sanco Seed treatment (ongoing)

- FOCUS Kinetics
- FOCUS “Landscape and mitigation”
- FOCUS - GW
- FOCUS - SW
- FOCUS - Air
- SANCO - Relevant metabolite
- Sanco -

Guidances in the regulatory risk assessment

- **Guidances allow to introduce “state of the art” (higher tier) in regulatory risk assessment**
- **Guidances need to be suitable for risk assessment purpose**

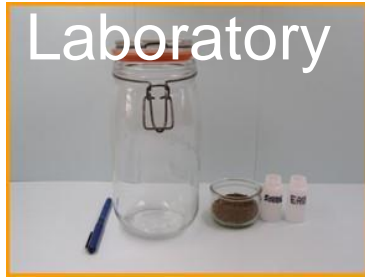
For sure; No way, Maybe ...



**It's very basic!
It must be improved !
To Something like that !**



Efsa “DegT50 Guidance” (2014)



- Evaluation of laboratory and field dissipation studies to obtain DT50
 - Provide methods to perform + derive DegT50 from field studies (OECD Guideline 232 _ 2016)
 - Provide guidance on selecting appropriated modelling endpoint (lab. vs field DT50, or combined)



European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

DT50: degradation rate parameter
KOC : adsorption parameter

Protected crops (Efsa 2014)

- Rank emissions of pesticides from protected crops (greenhouses, crops grown under cover) to relevant environmental compartments
- Shift from 0.1% emission to specific scenarios



Representativeness greenhouse scenario(s) ?

Specific Efsa GW greenhouse tomatoes, Italy (PISTOIA)

“The representativeness of the scenario for the purposes of risk assessment has not been established, either for Italy or for the rest of Europe.



...More work is needed to establish representative scenarios

Wrap-up

- **Tiered approaches for regulatory risk assessment: Higher tiers are frequent**
- **Higher tier = need “good lower tier” (i.e. soil selections)**
- **Drivers for performing higher tiers should always be made clear (exchange needed)**
- **Specific approaches are intrinsic to the process
// Guidances are needed to produce higher tiers (strong basis) suitable for Regulatory Risk Assessment – Reducing the uncertainty**

Thank you !



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