



# **MS experience with assessment methodologies Aquatic compartment**

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# Content

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- Context
- Evolution of aquatic risk assessment for last ten years: new methodologies and remaining concerns 📎 examples
- Discrepancies between EU and national conclusions
- Future needs and probable issues
- Conclusion

# Context

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- Aquatic systems: high protection goals by European Member states (e.g. Water Framework Directive 2000/60/EC)
- Aquatic ecotoxicology and research projects on aquatic ecosystems
- Data requirements increased in order to address new concerns (e.g. macrophytes)
- New methodologies.

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# **Evolution of aquatic risk assessment**

## **New methodologies and remaining concerns**

# Guidance documents: from SANCO to EFSA

1999

**HARAP** - Guidance document on higher-tier aquatic risk assessment for pesticides

2002

**Sanco/3268/2001**

2006

**EFSA** opinion - Acute and chronic risk to aquatic organisms (lowering the assessment factor)

2007

**AMPERE** workshop (Aquatic Mesocosms in Pesticide Registration in Europe)

2008

**RIVM** - Guidance for summarizing and evaluating aquatic micro- and mesocosm studies

2010

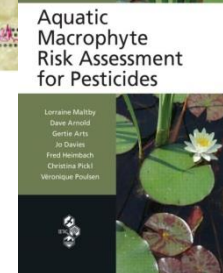
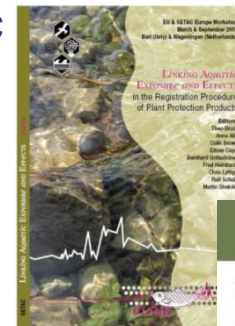
**E-link**: Linking Aquatic Exposure and Effects

2010

**AMRAP** – Aquatic Macrophyte Risk Assessment for Pesticides

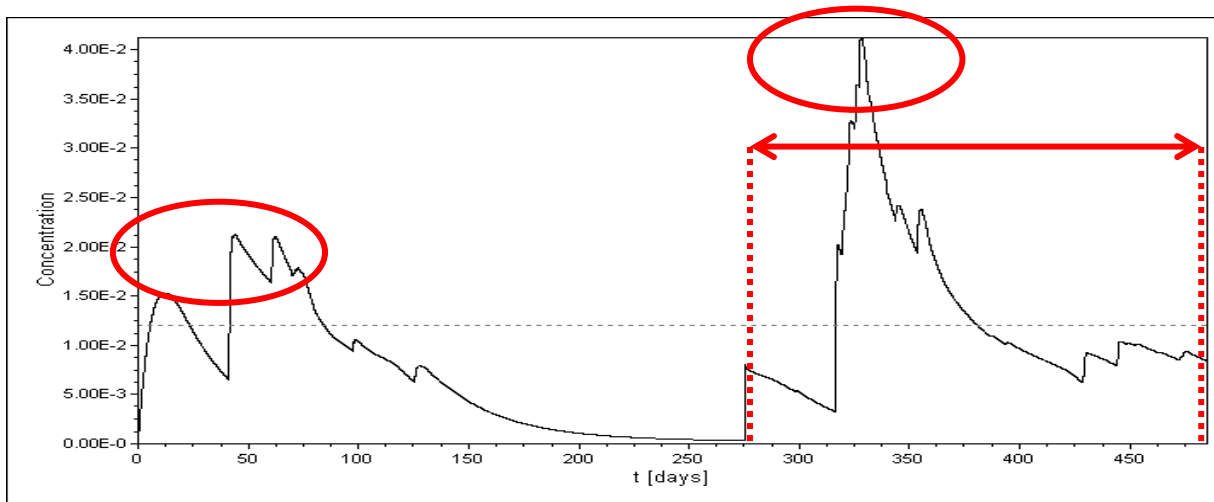
2013

**EFSA** Guidance



# Link fate and effects: modified exposure tests (1/3)

- Objective:
  - better reflect effects due to more realistic exposure of aquatic organisms,
  - conduct a more realistic risk assessment.



# Link fate and effects: modified exposure tests (2/3)

## Concerns:

- **Test design** directly related to FOCUS profiles  $\Rightarrow$  need for absolute confidence in FOCUS sw PEC values
- Questions related to **robustness** of FOCUS sw PEC calculations  $\Rightarrow$  need for FOCUS sw update to ensure more robust PEC values and risk assessment

# Link fate and effects: modified exposure lab tests (3/3)

- Recommendations:
  - Tested concentrations should cover FOCUS profiles for **all relevant scenarios** that need refinement (intensity and duration)
  - These profiles should be **presented** by notifiers in dossiers (monograph or dRR)



# Aquatic macrophyte pond tests (1/2)



- Outdoor pond tests conducted with macrophytes **questioned** for the following reasons:
  - Only initial and final endpoint measurements: did recovery occur?
    - ⇒ **What endpoint to use: NOEC/NOAEC?**
  - Should they be considered as cosms or kind of extended lab studies?
    - ⇒ **Should concentrations be expressed as initial or mean measured concentrations?**

# Aquatic macrophyte pond tests (2/2)

- Recommendations:
  - When possible, **add intermediate endpoint measurements** in order to show whether or not recovery occurs
    - And compare the NOEC/NOAEC to initial PEC values
    - Or compare the exposure in ponds to focus profiles
  - Discuss AF with RMS



- Representativeness of exposure evolved: **GAPs vs FOCUS PEC values**
- Better harmonisation of AF in the new guidance
- New **MDD** statistical method to assess and conclude on the effects observed in cosm studies: define more robust endpoints
- Keep in mind that a high level of **expertise** is still needed to assess these studies.

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# Discrepancies between EU and national conclusions

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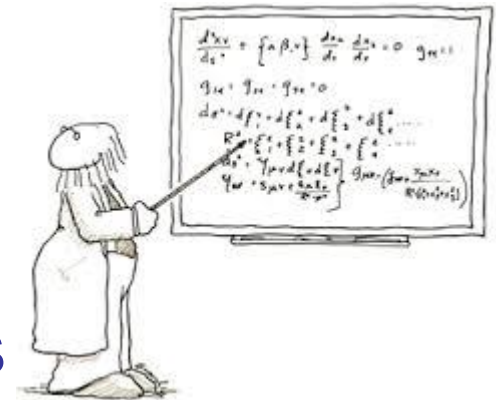
- Differences may be observed between the outcome of the risk assessment conducted at EU level and those conducted at national/zonal level:
  - consideration of **mitigation measures** that have to be taken into account at national level.
  - many studies are often submitted in the dossiers by applicants in order to **refine** the risk assessment
    - ⇒ **high workload** for member states.
    - ⇒ possible **different conclusion** (even within zones)

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# Future needs and probable issues

# Modelling: future tool?

- Modelling (TK/TD and ecological modelling) could become one of the major tools that will be developed and used
- Different views expressed:
  - MS opinions highly divergent
  - Need for additional competences
  - Difficult to “validate” models



⇒ **No model used in EU RA up to now**

# Possible way out

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- Development/validation of a **tool box** at EU level (SETAC/EFSA)
- **Training** of risk assessors
- Use in EU and zonal RA when relevant



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# Conclusion

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- Aquatic ecosystems: high level of concern by MS to improve water quality
- Constant improvement and evolution for many years thanks to research
- New tools popping up (e.g. modelling)
- Need for FOCUS sw update
- Need for common work

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**Thank you for your attention**