MS experience with assessment methodologies
Aquatic compartment

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Content

• 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

- 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.
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
**Objective:**

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

• **Test design** directly related to FOCUS profiles ⇒ need for absolute confidence in FOCUS sw PEC values

• Questions related to **robustness** of FOCUS sw PEC calculations ⇒ need for FOCUS sw update to ensure more robust PEC values and risk assessment
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
Cosms

- 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.
Discrepancies between EU and national conclusions
Discrepancies between EU and national conclusions

• 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)
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

• Development/validation of a tool box at EU level (SETAC/EFSA)

• Training of risk assessors

• Use in EU and zonal RA when relevant
Conclusion
Conclusion

• 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
Thank you for your attention