



Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters

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- Mandate received in December 2008
- Mandate revised in October 2012

The need for a modular approach:

- to cope with the complexity of the revision
- start with updating practical guidance on topics for which “building blocks” are available
- update in a later stage practical guidance on topics for which the “building blocks” are under construction

- Major needs identified for revision:
 - Harmonisation, therefore started in one WG for both mandates
 - Before start more detailed specific protection goals are needed, therefore work on „Opinion on specific protection goals“ (EFSA Journal 2010; 8(10):1821)
 - Update needed due to new Regulation (EC) No 1107/2009
 - Update needed considering new Data Requirements
 - Appropriate linking of exposure and effect assessment
 - More detailed guidance on higher tier RA

Updated mandate approved on 23 October 2012:

- 1. Guidance of the PPR Panel on tiered risk assessment for aquatic organisms in edge-of-field surface waters**
- 2. Scientific Opinion of the PPR Panel on the effect assessment for pesticides on sediment organisms in edge-of-field surface waters**
- 3. Scientific Opinion on the state of mechanistic effect modelling approaches for regulatory risk assessment of pesticides for aquatic organisms**

1. Guidance of the PPR Panel on tiered risk assessment for aquatic organisms in edge-of-field surface waters (*by July 2013*)

In particular, the following issues need to be addressed:

- Update the current guidance in view of the new Regulation 1107/2009
- Update the current guidance in view of the revised data requirements to Regulation 1107/2009
- Develop guidance on first tier aquatic effect assessment
- Develop guidance on higher tier aquatic effect assessment (based on laboratory studies and model ecosystem studies, guidance on design and evaluation of higher tier studies)
- Guidance on appropriate linking of aquatic exposure and effect assessment

This PPR Panel Guidance should be subject to a Public Consultation.

2. Scientific Opinion of the PPR Panel on the effect assessment for pesticides on sediment organisms in edge-of-field surface waters (2 years after acceptance of the revised mandate, i.e. October 2014)

A scientific opinion will be provided that describes the state of the art of effect assessment for sediment organisms. In particular the following issues will be addressed:

- Identification of standard test species
- Use of the geometric mean approach when toxicity data for a limited number of additional test species are available
- Use of Species Sensitivity Distribution approach for sediment organisms
- Use of the model ecosystem approach for sediment organisms
- Defining the ecotoxicologically relevant concentrations (ERCs) for acute and chronic risk assessment

3. Scientific Opinion on the state of mechanistic effect modelling approaches for regulatory risk assessment of pesticides for aquatic organisms (3.5 years after acceptance of the revised mandate, i.e. April 2016)

A scientific opinion will be provided that describes the state of the art of mechanistic effect modelling in the aquatic environment.

In particular the following state of the art of the following types of models will be addressed (for all aquatic water column and sediment dwelling organisms):

- Describe regulatory questions that can be addressed by effect modelling
- Describe model parameters that need to be included in relevant models and that need to be checked in evaluating the acceptability of effect models
- Describe available effect models for aquatic organisms, in particular
 - Toxicokinetic / toxicodynamic models
 - Mechanistic population models
 - Mechanistic food web models
- Secondary poisoning
- Ecosystem models representative for ditches, ponds and streams
- Selection of focal species
- Development of ecological scenarios that can be linked to the regulatory defined water bodies in the climatic zones of Europe

- Consultation with Risk Managers via questionnaire end 2008, consultation on SPGs in May 2011 and Nov 2012
- Public Consultation on existing SANCO GDs for Aquatic and Terrestrial Ecotoxicology Oct-Dec 2008
report: EFSA Journal 2009; 7(11):1375 [129 pp.].
- Public Consultation on draft GD on tiered RA for aquatic organisms in edge-of-field surface waters Dec 2012-Feb 2013
report: EFSA supporting publication 2013:EN-460.162 pp.
➤ *Presentation Tom Meyvis (agenda item 3)*

Overview of guidance document on tiered risk assessment for aquatic organisms in the edge-of-field surface waters

- Chapter 1: Reading Guidance
- Chapter 2: Executive Summary
 - Serves as overview of the guidance for day to day use
 - To be used only once familiar with the background
 - Cross-references to the relevant sections in the main guidance where all background information and scientific reasoning is provided

Chapter 3: Introduction

- Legislative background
- Objectives
- Focus and restrictions of the GD
 1. *Scope of RA*
 2. *Aquatic organisms living in the water column*
 3. *Spatial Scale: edge-of-field surface waters*
 4. *Use of effect modelling and combination to exposure modelling*
 5. *Freshwater vs marine organisms*
 6. *Endocrine Disruption*
 7. *FOCUS exposure assessment methodology*
 8. *Chemical and biological monitoring*
 9. *Permanent water bodies vs water bodies falling temporarily dry*
 10. *Active substances with new modes of action*

Chapter 4: The tiered approach, risk assessment terminology and linking exposure to effects

- *The tiered approach*
 - *Terminology in the aquatic risk assessment of PPPs*
 - *PPP effect assessment schemes*
 - *When to use the peak or a time-weighted average concentration in the risk assessment?*
- *Presentation Theo Brock (agenda item 4)*

Chapter 5: Exposure Assessment Goals and Specific Protection Goals

- *The Ecotoxicologically Relevant Concentration (ERC)*
- *Exposure assessment goals in edge-of-field surface waters*
- *Specific Protection Goals for aquatic organisms*
- *Vulnerable species*
- *Implementation of exposure assessment goals and specific protection goals in this guidance document*

➤ *Presentation Theo Brock (agenda item 4)*

Chapter 6: Exposure Assessment

- Brief description of FOCUS sw scenarios and models
- The PPR Panel did not evaluate or change the current exposure assessment methodology using FOCUS surface water tools
- The PPR Panel assumes the current methodology will continue to be used until a new/revised methodology becomes available

Chapter 7: Data requirements for active substances and formulations and tier-1 effect assessment

- Introduction to data requirements and related OECD guidelines
 - Standard toxicity tests with aquatic organisms
 - Deriving Regulatory acceptable concentrations (RAC)
 - Further testing on aquatic organisms
 - Specific requirements for formulated products
 - Bioconcentration and secondary poisoning
- *Presentation Dan Pickford (agenda item 5)*

Chapter 8: Higher-tier effect assessment on basis of laboratory toxicity tests with standard and additional species

- Geometric mean – AF approach
- The Species Sensitivity Distribution (SSD) approach
- *Presentation Dan Pickford (agenda item 6)*

Chapter 9: Higher-tier effect assessment by means of refined exposure laboratory tests and experimental ecosystems

- Selecting the appropriate exposure regime
- Refined exposure laboratory tests
 - Reasons to use them, guidance how to use them
 - *Presentation Dan Pickford (agenda item 6)*
- Model ecosystem approach
 - Designing mesocosm studies
 - Interpreting mesocosm studies
 - Derivation of RAC using the threshold and recovery approach

➤ *Presentation Theo Brock (agenda item 7)*

Chapter 10: Non-testing methods, Metabolites, Impurities and Formulations with more than one active substance

- *Non-testing methods*
 - Mainly QSAR, read across
 - *Metabolites and degradation products*
 - Scheme and description on when/which testing is needed, and when non-testing methods could be applied
 - *Combinations of active substances in formulations*
 - Assuming concentration addition
- *Presentation Dan Pickford (agenda item 8)*

Chapter 11: Other issues

- Test batches / impurities
- Testing difficult / poorly soluble substances
- Promising mechanistic effect models
- Reduction of (vertebrate) testing
- Differences in risk assessment procedures between Regulation (EC) No 1107/2009 and the Water Framework Directive (WFD)

Chapter 12: Addressing uncertainties

- General way on how uncertainties especially for higher tier tests can be addressed in a qualitative way
- Examples are provided in Appendix G

- A. Elements of the exposure assessment goals related to the choices made in the FOCUS_{sw} scenarios
- B. Background of the procedure for partitioning of substance between water and sediment in the FOCUS_{sw} step 2 exposure calculations
- C. Comparison of acute rainbow trout toxicity with acute toxicity values for amphibian species
- D. Information on life cycle characteristics for aquatic organisms
- E. Variability in exposure–response relationships between micro-/mesocosm experiments performed with the same plant protection product

F. Minimal detectable difference (MDD)

G. Worked examples for qualitative uncertainty evaluation

H. Case studies

- performed using 3 model compounds and for 1 compound also for its metabolites
- to check the guidance and show how to use it, e.g. for:
 - *Geomean*
 - *SSDs*
 - *Mesocosm study*
 - *Metabolite RA*

Agenda of this Info Session

- As mentioned before today more detailed presentation of terminology, protection goals, various tiers
- Tomorrow morning presentation of case studies on how to apply the guidance
- Q&A session