Outcomes of the workshop

„Reflecting on the increasing complexity in environmental risk assessment of Plant Protection Products”

AIM  Tackle the issue of increasing complexity of the environmental risk assessment from a scientific and a regulatory point of view.

Science behind ERA (e.g. calibration of new methods) should be part of a GD rather than being developed in the course of the ERA of individual substances.

Limit complex higher tier refinements

• Base evaluations on the worst-case intended uses,
• Ideally should be addressed at EU level and not for specific compounds or PPP,
• Ideally should not be accepted at MS level if beyond existing harmonised guidance,
• For some participants: keep the ERA as standardised as possible by comparing all PPP to the same point in a ERA scheme ideally validated/calibrated by monitoring data, to:
  • limit the influence of noise in higher tier refinements and expert judgement;
  • target at excluding PPP with highest risks, e.g. define “cut-off” points for refinement.

Examples of how to optimise the procedure

• Improve guidance / develop stricter guidance for “oriented/ targeted higher tier”.
• Follow the tiered approach in the RA and keep RA as simple as necessary, i.e. more emphasis on established lower / intermediate tier refinement options.
• Improve sharing and networking (e.g. spreadsheets for generic refinements).
• Allow for 1) suitable time-frame so that new developments are enabled, and 2) complexity only when it is really necessary (fit for purpose).
• Provide training and workshops to RA on some aspects of complexity (e.g. EFSA).
• Involve risk assessors more systematically in the development of GD and tools.
• Use tool-box on e.g. agreed models (provided e.g. by EFSA).
• Improve transparency between active substances and PPP evaluation.

Proposed “ways out”

• For some participants: Give RMM a larger importance in the assessment, i.e. couple better RMM with the ERA, e.g. by implementing systematically compensation areas or accepting higher tier assessment only to establish the authorisation requirements.
• Need for a larger spectrum, more elaborated and better evaluated RMM, e.g. SUD.
• More complex higher tier assessments could be partly avoided by having RMM implemented earlier in the process.
• Are higher tier studies to avoid or reduce risk mitigation measures acceptable?
• Need to balance protection goals and granting authorization.
• Note: RMM is applied at local scale but decision and regulation are at regional / national scales.
• More complex models increase awareness of uncertainties = identification of more risks.
• Uncertainties when extrapolating from one safe scenario in the EU to a representative scenario in MS.
• More data increase ERA robustness.
• Cannot be totally avoided but should be reduced or at least not increased.
• Risk Mitigation Measures

Protection goal and protection level

• Setting PGs should be rather an iterative process.
• Should PG be fulfilled at EU level only, or at both EU and MS level?
• Need to balance protection goals and granting authorization.
• A high level of environmental protection should be maintained.

Risk Mitigation Measures

• Complex higher tier assessments could be partly avoided by having RMM implemented earlier in the process.
• Are higher tier studies to avoid or reduce risk mitigation measures acceptable?
• Possibility to couple better RMM with the ERA.
• Need to evaluate the effectiveness of the different RMM options.
• Need to develop (more / better) RMM options for the terrestrial compartment.
• More complex models increase awareness of uncertainties = identification of more risks.
• Need to balance protection goals and granting authorization.
• Note: RMM is applied at local scale but decision and regulation are at regional / national scales.

Main issues raised

General perception on increased complexity in ERA

• Challenging issue in ERA, management and communication.
• Complexity is linked to refinements in higher tier risk assessment.
• Cannot be totally avoided but should be reduced or at least not increased.
• If it improves the ERA scheme, it is generally justified.
• Workload is not matching with time-frame and effective use of resources.

Information related to Complex higher tier issues to be addressed:

• Whenever delivered:
• Mostly at EU level (i.e. not shifted to MS) = focus on realistic worst-case/representative higher tier studies.
• Not for specific substance or PPP (i.e. only generic).

Uncertainties

• Simpler models can hide uncertainty = need for tiered assessment.
• More data increase ERA robustness.
• Uncertainty analysis should be part of the ERA.

Monitoring

• Could be used for refinements (as high tier data) and calibration of the scheme.
• Should only be used retrospectively for validation of general ERA scheme and decision-making.

Comparability

• Increasing complexity in ERA makes transparent risk communication challenging
• General need for more transparency in the documentation of the ERA procedures = would facilitate the communication between various stakeholders.

Legal task

• To address realistic exposure and thus common practices / whole system.

Other type of cut-off criteria

• Hazard assessment not suitable for addressing ERA issues and should not be used to reduce complexity.
• New types of cut-off criteria limiting the “unless clause” might be of relevance (e.g.: Once a safe use is proved, stop refinement).

Guidance and time / resources

• Too much room for interpretation/expert judgement = disharmonized RA at MS levels.
• Need for suitable GD for evaluation of complex higher tier studies and approaches
• Need for improvement of GD: new knowledge to be integrated into existing guidance
• Detailed GD: needed for evaluating High tier studies / requires resources to be used.

If it improves the ERA scheme, it is generally justified.
• Workload is not matching with time-frame and effective use of resources.

To address realistic exposure and thus common practices / whole system.

Main issues raised

Dialogue on science: Scientific information to be considered:

• Whenever delivered in the process.
• When drafting guidance.
• No new “company-specific” scientific considerations.

Increasing complexity in ERA scheme

Acceptable if aims at better ERA, e.g.
• eliminating blind spots (e.g. dust, amphibians)
• Validating models/new methods.
• May not be acceptable:
  • if aims at refining single aspects of RA
  • due to uncertainties, comparability, time, resources.

Transparency and risk communication

Comparative assessment is currently relevant only in the frame of authorisation of PPP with Candidates for Substitution.

Reduction in comparability when increase in data for some PPP = unbalanced perception of the risk and difficulties to rank / discriminate according to the toxicity of PPP.

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