

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

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

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

- 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

Comparability

- 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.

Legal task

- Is to apply current legislation in relation to single PPP.
- Is 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.

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.
- 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.

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.

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.

Proposed “ways out”

Science

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.
- Improve communication between Risk Assessors and Risk Managers.

Risk Mitigation Measures

- 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.
- Note: RMM is applied at local scale but decision and regulation are at regional / national scales.



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