Disclaimer

The content of this presentation does not reflect the view of the Swedish Chemicals Agency.

The presentation merely reflects the current (November 19, 2014) status/outcome of an internal project, which is aimed to review and at best to improve the risk assessment and authorisation process of plant protection products.

Shortcomings in current risk assessment – Are we on the right track?

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Swedish Chemicals Agency

CKB Workshop
Current status and development of methods for detecting field level effects of pesticides in aquatic ecosystems
SLU, November 19, 2014

Is it possible to ”clearly establish” that this…

cause ”no unacceptable impact”?

Analysis of the current methodology - concepts

- Legal requirements:
  1. Evaluation should be based on scientific principles – requires valid and reliable method
  2. Take into account / evaluate uncertainties.

- Object for analysis:

  The prospective tiered-approach for risk assessment as described in EFSAs guidance documents

Analysis of the current methodology - concepts

- Validity: How well does our method predict what we expect it to predict? Requires a certain degree of reliability.
- Reliability: How reliable is the method in giving similar results regardsless – influence of evaluator and uncertainties.
- The specific vs. the general: How to make conclusions about the general from information about the specific.

Characteristics of the current method - reliability

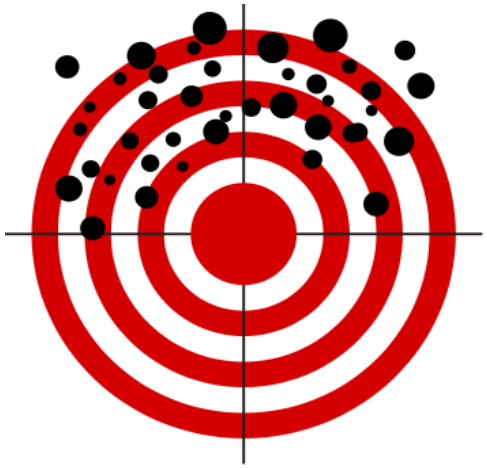
- Increasing complexity
- Dependent on expert judgment/assumptions
  - Different outcomes among assessments
    - Applicants vs MS vs other MS
  - Reduces comparability between assessments
  - These effects are worsened by complexity

  → Negative impact on reliabilty

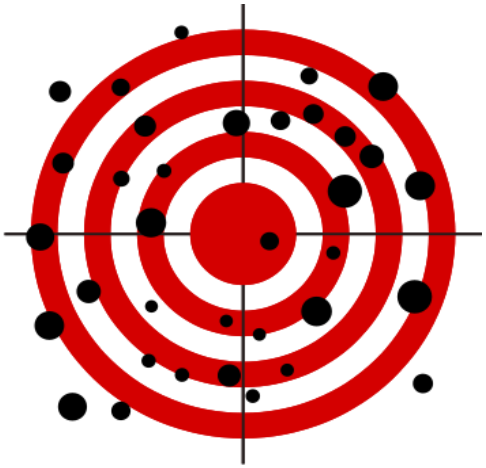
- Low reliability gives a low validity

Characteristics of the current method - validity

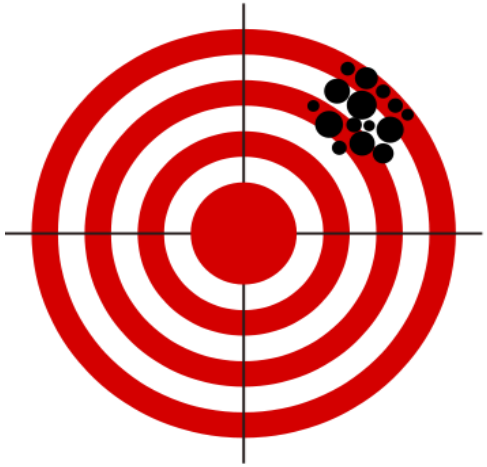
- Operational targets are defined – the risk assessment generate a risk ratio
- Uncertainties remain and are not quantified
- Method not validated



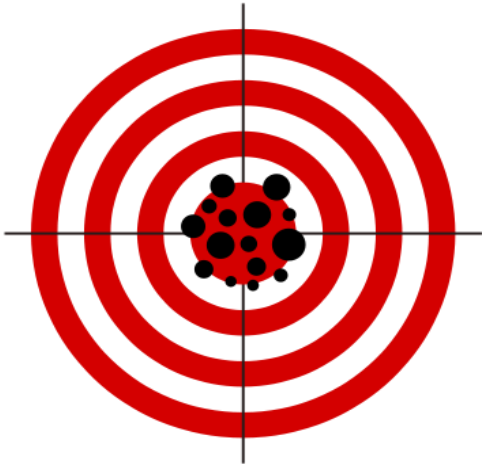
Unreliable & Unvalid



Unreliable, But Valid

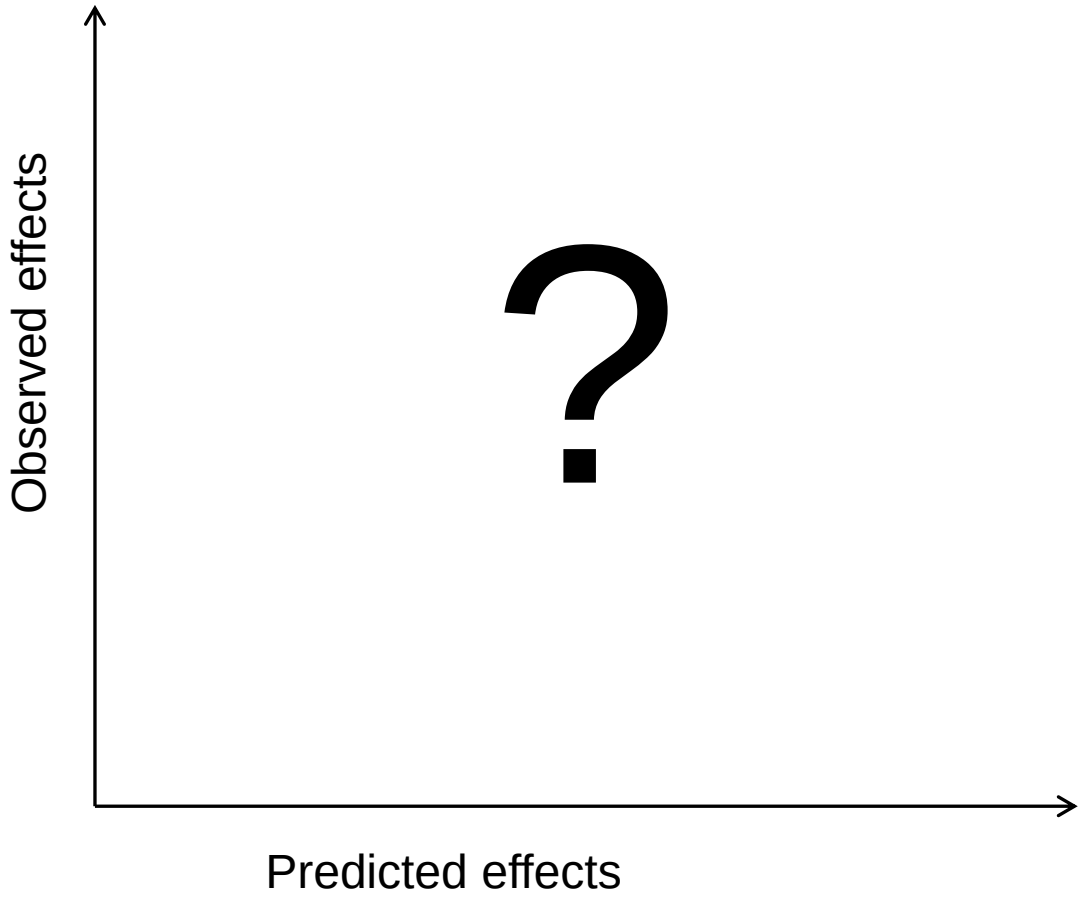


Reliable, Not Valid



Both Reliable & Valid

Validity of the method – what can we expect?



Uncertainties

- Model uncertainties
  - model assumptions; both effect and exposure side
  - input parameter uncertainty

Uncertainties

- Extrapolation to field conditions
  - Mixture effects between >1 chemical
  - Interaction
    - Interactionbetween PPP and Environmental stressors
    - Inter- and intra species interaction
  - Sensitive species is not included in conventional test system
  - Carry-over toxicity from sequential exposures
  - Assumption that 95% of the species protects the system

Uncertainty propagates

- Potentially low validity in exposure assessment
- Biological systems – generally low validity
- Remaining uncertainty is expected to further reduce validity

Why refinements may lead us in the wrong direction

- There is no reference point in terms of absolute risks
  - We are providing more information on one input parameter without knowledge of the overall validity of this adjustment
- Refinement hampers comparability/reliability, which is a prerequisite for a valid method
- Involves expert judgment – introduces variability and lowers reliability

→ Puts too much confidence in the specific – we lack knowledge about how new, non-validated assumptions affect the overall assessment

Conclusion

- Probably low overall validity due to complexity of the system
- Few validating data
- The tiered risk assessment process contains elements that hampers reliability

- In the authorisation process it is important to correctly rank products according to risk

→Characteristics of an appropriate method under such circumstances?

Requirements of an alternative method - examples

- More standardized and hence more robust
- Limit the number of predictors
- Minimize need for expert judgment in individual cases
- Validating data

Advantages of an alternative method - examples

- Facilitates harmonization between member states
- Legal advantages
  - Better tools to ensure equal treatment of applicants
  - Higher predictability of decisions
- Increased overall efficiency of the process
- More efficient risk management
- Increased transparency