

# *Treatment and Expression of Uncertainties in Risk Assessment*

Workshop 2  
January 27<sup>th</sup>

**Chair:** Michel Petit

**Rapporteur:** Wolfgang Dekant, channeled through  
Nancy Beck

**Heavy Lifting:** Andy Hart

## *Acknowledgments*

- EU: Andy Hart, Jim Bridges, Peter Calow, Jan Linders, Wolfgang Dekant, Theo Vermeire, David Gee, Tony Hardy, Vladimir Garkov, Takis Daskaleros
- US: Vicki Dellarco, Linda Abbott, Nancy Beck, Marcus Aguilar
- Canada: Hans Yu, Titus Tao, Scott Jordan, Myriam Hill, Peter Chan, Ed Black, Laurent Gemar, Tyler LaCombe, John Giraldez

# *Opening Questions*

- What do Risk Managers want? Will this work for them?
- Need guidance for risk managers.
- Need to ensure that the analysis is tailored to the objectives of the assessment.
- Can the tables apply to categorical and probability based assessments?
- Need templates for different sources of analysis



# *Opening Questions*

- Need to do a sensitivity analysis to prioritize uncertainties for further analysis.
- Need to account for level of extra uncertainty (eg uncertainty in standard approach vs novel information)
- How can we collect empirical information on uncertainty
- How can we ground truth uncertainties
- Need trust with authorities and other stakeholders

## *Risk Manager Needs*

- Ability to make a decision with a reasonable assurance of no regret.
- Risk Manager wants, may not be what the risk manager needs (e.g., a single point estimate).
  - How do we get the risk manager information in a clear and transparent manner which will not overwhelm or scare them.
  - How much information is the right amount of information.
  - More information does not always help make the decision.
  - Need a dialogue with risk managers.

## *Positive Aspects of the Framework*

- Can easily incorporate problem formulation to understand what decisions will be informed.
- Information provided to risk manager can be tailored to the managers interest.
  - Risk Manager summary can be supported by summary tables and further detailed uncertainty tables (for both quantitative and categorical questions)



## *Positive Aspects of the Framework*

- Provides transparent presentation of what risk assessors should currently be looking at.
- Gives a way to list uncertainties in a clear manner to help inform decision makers, inform future research, identify large gaps, inform sensitivity analysis
- Framework can be used for risk *or benefit* analysis including human and ecological endpoints.
- Forces risk assessor to think about defaults

## *Positive Aspects of the Framework*

- Improves transparency
- Approach can work for screening level or complex assessments. Should include test cases of both.
- Allows for inclusion of newer, perhaps 'non-validated data (e.g. -omics) as uncertainty associated with data can be clearly articulated.
- Allows for flexibility in scaling and terminology to meet data need and risk manager preferences.



## *Important Considerations*

- Uncertainty should not be used as a tool for inaction; risk assessors and risk managers need to be educated on how to deal with it.
- While it is important to state which uncertainties we cannot quantify; some believe there should never be unquantifiable uncertainties- -we should always try to provide some bounds. (a range of views exist here)

## *Important Considerations*

- A good decision can still have a bad outcome.
- A “no regret” standard is nearly impossible.
- We must take care to not to overstate our certainty in the uncertainty.

## *Bottom Line*

- No deal breakers identified; only slight modifications to the framework were identified.
  - Caveat: Risk managers did not identify themselves so their feedback is still much needed.



# *Needs*

- Guidelines/templates
  - Allowing for discussion between RA and RM
  - Allowing for clear statement of questions to be answered
- Implementation Manual
  - Code of good practice
  - Pilot implementation strategy; training

## *Next Steps*

- Put finishing touches on guidelines (including problem formulation)
- Get risk manager feedback to ensure that the information the framework provides will be useful to them and easy to incorporate into decision making.
  - Need to brainstorm outreach opportunities

## *Next Steps*

- Conduct prospective case studies (using the framework for risks and benefits) incorporating this approach for the presentation of uncertainty information through to implementation by risk manager. Perhaps EU scientific committees can do some of this work. Concept of grants and funding was mentioned.
  - May take 6 months-1 year (or more)



## *Next Steps*

- Strive for a best practices document (format not determined yet) based on case study outcomes.
- Workshop to discuss and review.

## *Overall Conclusion*

- A helpful tool
- Is not disruptive of current approaches
- Format is useful for understanding certainty of the outcome evaluated.
- Getting risk management feedback is a necessary next step before moving forward.

**This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumers DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**