Assessing and communicating uncertainties for risk assessment and risk management: recent international developments

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Some recent developments…

- Codex Working Principles for Risk Analysis, 2003-
- EFSA Uncertainties in Exposure Assessment, 2006
- IPCS Uncertainties in Exposure Assessment, 2008
- ECHA REACH Guidance, Chapter R19, 2008
- IPCS Uncertainties in Hazard Characterisation, 2014
- EFSA Draft Guidance on Uncertainty, 2015
- *and others*…

Example 1: Red River

Red River Flood, Grand Forks USA, 1997

- Levee height: **51 feet**
- River height *prediction*: **49 feet**

- **Actual flood height: 54 feet**

After: Nate Silver, The Signal and the Noise, 2012

Example 1: Red River

Red River Flood, Grand Forks USA, 1997

- **Cost: $3-4 billion + credibility & trust**

Example 1: Red River

Red River Flood, Grand Forks USA, 1997

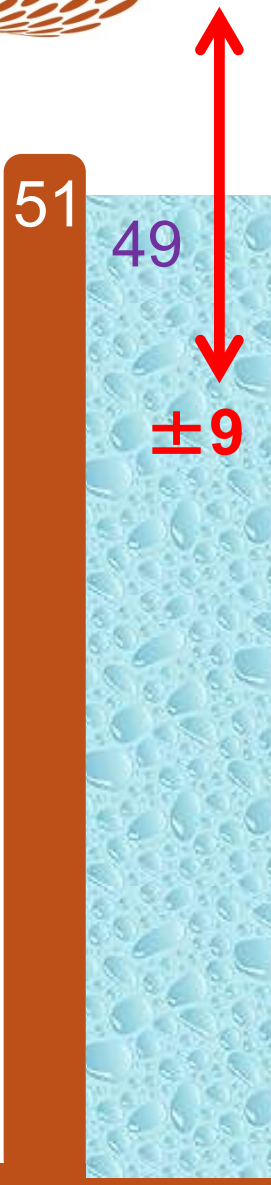
- Levee height: **51 feet**
- River height *prediction*: **49 feet**

- **Uncertainty: ±9 feet** (Silver 2012)

Example 1: Red River

Risk managers and stakeholders need to know:

- ***How much*** higher might the river rise?
  - *Quantitatively*
  - Taking account of *as much of the uncertainty as possible*
- ***How likely*** is it to exceed the levee height?



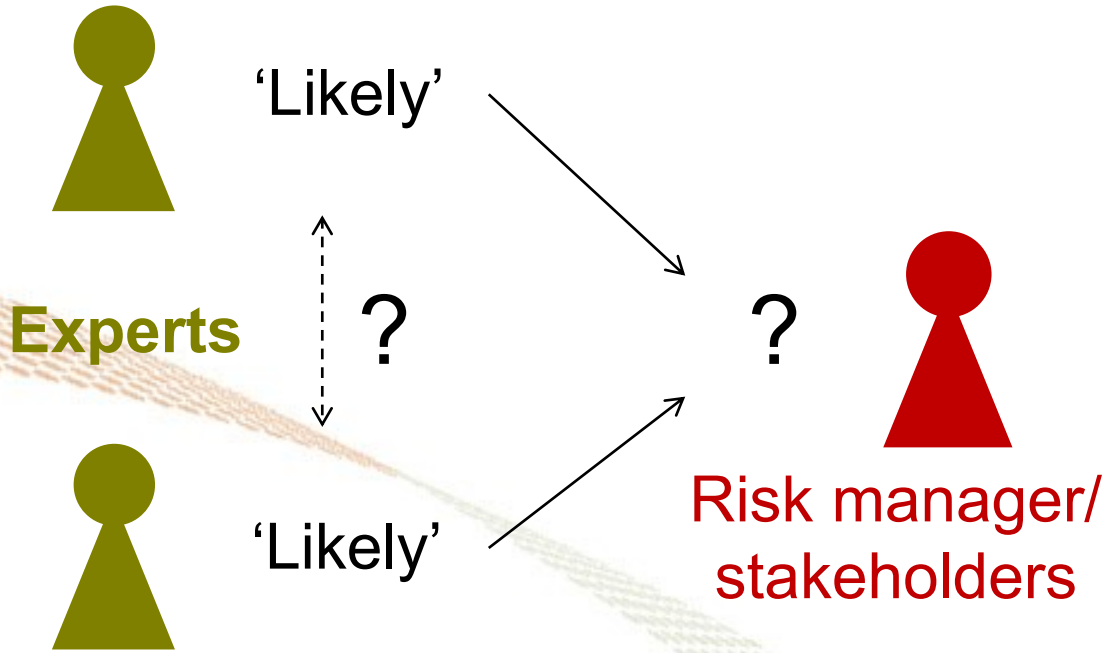
Example 2: ‘Likely’

- **What probability do you associate with the word ‘Likely’?**

- *Write down your probability, expressed as a percentage between 0 and 100%*

Example 2: 'Likely'

- Words are *ambiguous* – mean different things to different people



Macleod & Pietravalle

Example 3: Bin Laden

President Obama: "Some of our intelligence officers thought that it was only a *40 or 30% chance* that Bin Lade… in the …

Quantify likelihoods if possible
- For expert judgements as well as statistical estimates

"At the co… fairly lengthy discussion where…

Different experts may give…
- This is okay - and *importa…*

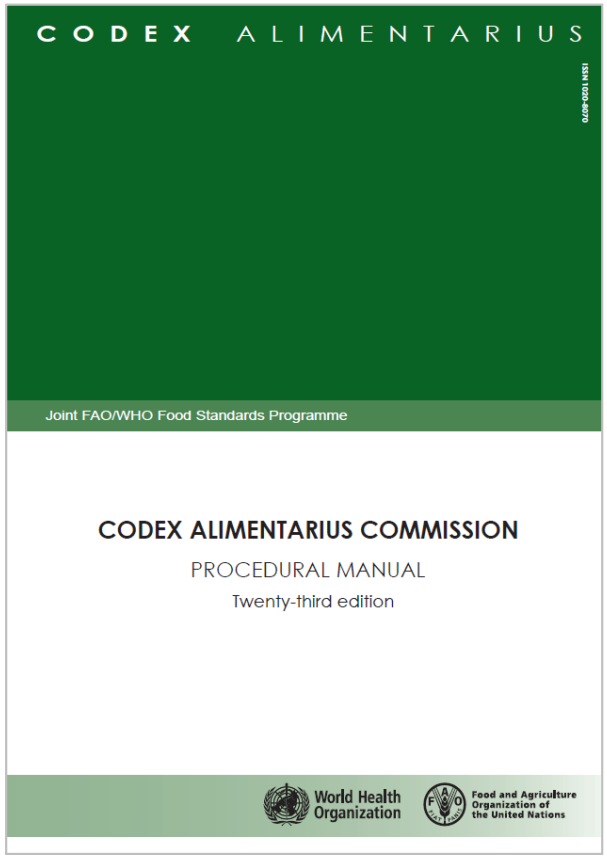
And it's *the risk manager's job* to decide what to do about it

"W… …ht it wa… *was wo…*

Ultimately it's the risk managers' understanding of the uncertainty that will matter

Key principles

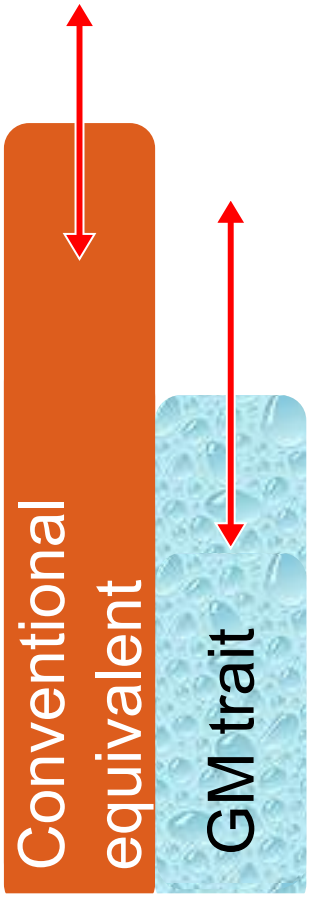
- ‘Uncertainties…should be explicitly considered at each step in the risk assessment and documented in a transparent manner’
- ‘Expression of uncertainty…may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable’
- ‘Responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors’



Codex Working Principles for Risk Analysis (2003-)

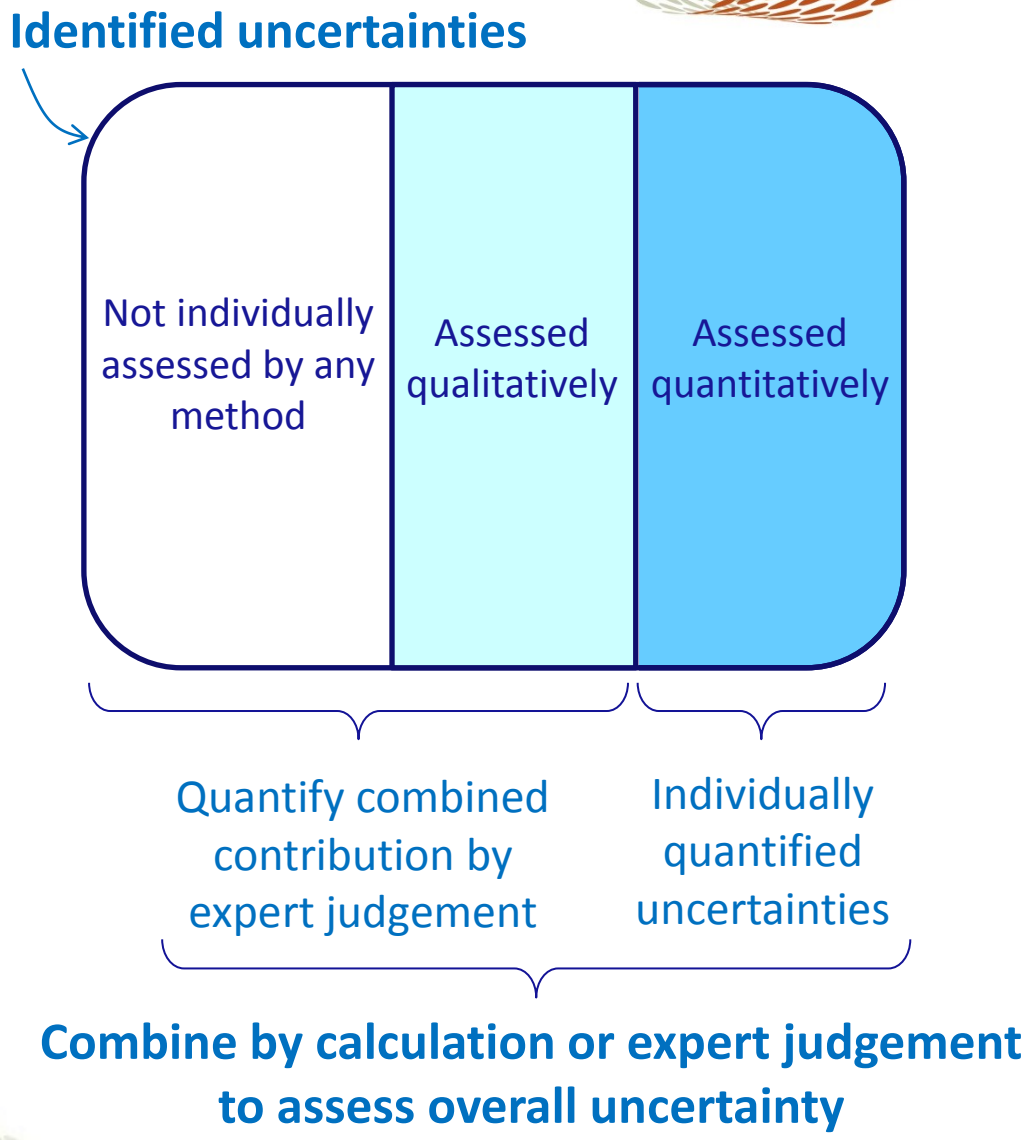
The same principles apply to all EFSA's scientific advice

- *How different* might the outcome be?
- *How likely* are the outcomes of interest to risk managers?
- *Quantify* as much of the uncertainty as possible
- Leave risk management to risk managers



Draft EFSA Guidance (2015)

- Systematic identification of uncertainties
- Flexible toolbox of assessment methods
  - Qualitative and quantitative
- Start simple; refine as far as needed
- Express overall uncertainty quantitatively



Example: T-2 and HT-2 toxins

- *Hazard*: Tolerable Daily Intake (TDI) = 100 ng/kg bw/day
- *Exposure*: 95th percentile for Toddlers (12-36 months)
  - 23 ng/kg bw/day assuming non-detects are zeroes
  - 91 ng/kg bw/day assuming non-detects = limit of detection
- *Other sources of uncertainty* assessed qualitatively

Sources of uncertainty	Direction[(a)]
Uncertainty of the analytical measurements	+/-
Occurrence data on feed not representative for all feed materials in which T-2 and HT-2 toxins could be present	+/-
Effect of food and feed processing	+/-
High variability of feedstuffs used and feeding systems for livestock	+/-
Use of UB occurrence data in the exposure estimations	+
Use of LB occurrence data in the exposure estimations	-
Limited exposure data on infants	+/-
Limited data on exposures for vegetarians	+/-
No toxicokinetic data on T-2 and HT-2 toxins in humans and in most animal species	+/-
Lack of information on the contribution of the toxicity of HT-2 toxin and other metabolites to overall toxicity	+/-
Combined effects with other mycotoxins or other toxic substances in food and feed	+/-

(a): + = uncertainty with potential to cause over-estimation of exposure/risk; - = uncertainty with potential to cause under-estimation of exposure/risk

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- Expert judgement of *overall uncertainty*:

The CONTAM Panel concluded that given the uncertainties, the risk assessment of human and animal exposure to the sum of T-2 and HT-2 toxins is more likely to over- than under-estimate the risk.

- This is a quantitative judgement: *<50% probability that risk is under-estimated*
- Panel also concluded '*No health concern*'

Many assessments already imply quantitative judgements about overall uncertainty

Defined scales may help…

- EFSA suggests an optional scale for probabilities
  - adapted from a similar scale used by IPCC*

Probability term	Probability range
Extremely likely	99-100%
Very likely	90-100%
Likely	66-100%
As likely as not	33-66%
Unlikely	0-33%
Very unlikely	0-10%
Extremely unlikely	0-1%

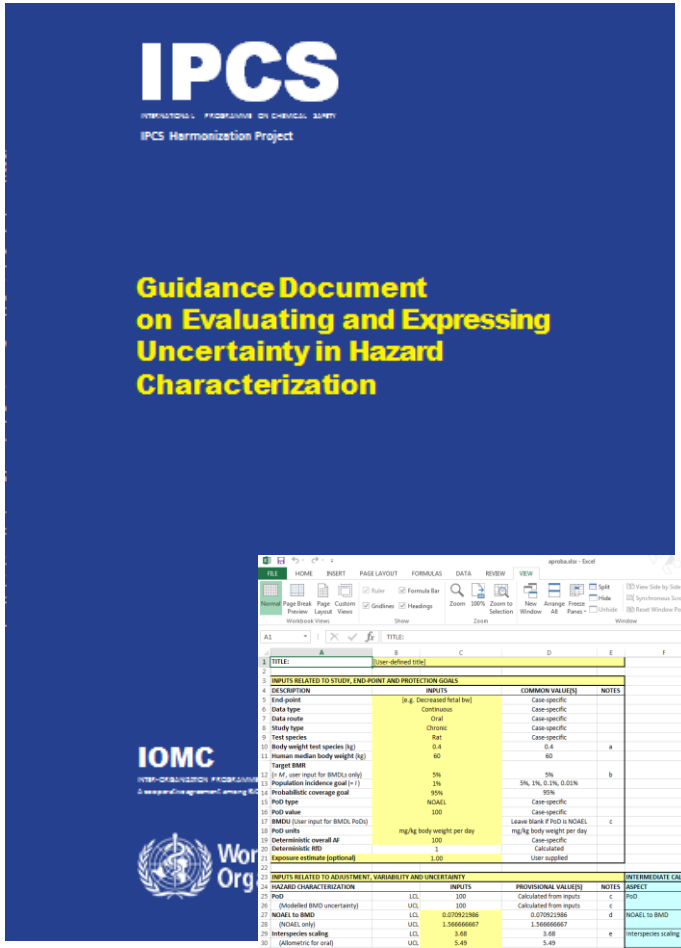
- Record the rationale for judgements
- Consider using formal expert elicitation techniques

Limits to quantification

- EFSA Draft Guidance recognises assessors may not always be able to quantify overall uncertainty
  - In such cases, they should *not* give qualitative expressions that imply quantitative judgements
  - Instead, they should:
    - Report that the *overall uncertainty cannot be quantified*
    - Consider *partial quantification*, conditional on assumptions about the unquantified uncertainties
    - *Highlight & describe* the unquantified uncertainties

IPCS Guidance (2014)

- Focus on uncertainty in chemical hazard characterisation
- Guidance and Excel spreadsheet tool



IPCS Guidance (2014)

- **Quantifying uncertainty requires precise definition of the parameter to be estimated**
- Existing reference doses are ambiguous
  - E.g. Tolerable Daily Intake = ‘dose that can be ingested daily over a lifetime without posing *significant risk to health*’
- IPCS Guidance defines $\mathbf{HD_M^I}$: the **Human Dose** at which a fraction (or incidence) **I** of the population shows an effect of magnitude (or severity) **M** or greater

IPCS Guidance (2014)

- Quantifies uncertainty of HD_M^I based on:
  - Databases on intra- and inter-species variation for multiple chemicals
  - Statistical modelling
- Example: Deoxynivalenol
  - BMDL10 for body weight = 170 µg/kg bw/day
  - Conventional reference dose = 1.7 µg/kg bw/day
  - HD_{05}^{01} : 90% CI = 0.44 – 19.2 µg/kg bw/day
  - Probabilistic reference dose = 0.44 µg/kg bw/day
  - Conventional reference dose has 68% coverage

Implications for risk assessors

- *Need to apply the Codex Working Principles*
- EFSA Guidance provides a general toolbox
  - flexible and scalable to the needs of each case
  - basic approaches require expert judgements comparable to current assessments, with increased transparency
- IPCS Guidance offers specific tools for chemical hazard characterisation
  - similar initiatives may be needed in other areas
- Training and specialist help will be needed

Implications for risk managers & stakeholders

- Better information on uncertainty
  - Range and likelihood of possible outcomes
  - Identify and describe unquantifiable uncertainties
- More transparency about:
  - Justification for expert judgements
  - Variation in expert opinion
- Better basis for decision-making
  - Including participatory approaches
- More transparency about how the impact of uncertainty on decision-making is resolved

Challenges ahead

- Culture change for risk assessors & managers
  - Recognition of need
  - Understanding of roles
  - New methods
  - Quantification

- Communication
  - New strategies needed