







NEW GUIDANCE DOCUMENT

- For use in all areas of EFSA's work
- Final version will be mandatory
 - Part of EFSA's commitment to transparency
- Draft for Public Consultation
 - Closes 10 September 2015
- 1-year Trial Period before final version
 - Each Panel to try at least one assessment





WHY ADDRESS UNCERTAINTY?

- All scientific assessments are uncertain
 - Some are more uncertain than others
- The degree of uncertainty affects the likelihood of adverse outcomes
 - More uncertainty → higher risk of adverse outcome
 - Less uncertainty → lower risk of adverse outcome
- So, uncertainty has important implications for decision-making





WHY ADDRESS UNCERTAINTY?

- Resolving the impact of uncertainty on decisions is the responsibility of decisionmakers, not scientists
 - It involves value judgements about how sure society wants to be
 - What level of risk is acceptable
 - What management actions are proportionate
- Therefore scientists must characterise uncertainty, to inform decision-making
 - What is the range of possible outcomes?
 - What are their relative likelihoods?





MANDATORY BUT FLEXIBLE

Mandatory

- Apply Guidance
- List identified uncertainties
- Characterise their impact on overall assessment outcome
- Clear & unambiguous

Flexible

- Choice of methods
- Degree of refinement
- Scalable to time and resources available
- Fit for purpose





MAIN STEPS OF UNCERTAINTY ANALYSIS

- Identify uncertainties
- Describe uncertainties
- Characterise uncertainty:
 - individual uncertainties
 - overall uncertainty
- Sensitivity analysis
- Reporting

Flexibility:

- Start simple
- Refine as far as needed
- ...or as far as time & resources allow
- Short cuts for:
 - Emergencies
 - Standardised assessments





CHARACTERISING UNCERTAINTY

Qualitative and quantitative approaches

Flexibility: use what suits your assessment

- Qualitative methods include: descriptive, ordinal, matrices, NUSAP, uncertainty tables
- Quantitative methods include: assessment factors, uncertainty tables, interval analysis, probability bounds, confidence intervals, Bayesian inference, bootstrap, Monte Carlo, Imprecise probability, Bayesian analysis...
- Guidance on pros & cons, and how to choose

MHASis





CHARACTERISING UNCERTAINTY

- It is not necessary to characterise all uncertainties individually
- It is necessary to characterise overall uncertainty
 - This is what matters for decision-making
- Overall uncertainty should be quantified as far as is scientifically achievable





CHARACTERISING UNCERTAINTY

Quantify as far as is scientifically achievable

WHY

- Qualitative expressions are ambiguous
 - Likely' means different things to different people
- ...and often imply risk management judgements
 - e.g. negligible, no concern, etc.
- Many decisions involve quantitative comparisons
 - E.g. is acceptable limit exceeded?
- Quantified uncertainties can be combined by calculation
 - More rational & reliable than other methods





CHARACTERISING UNCERTAINTY

- `...as far as is scientifically achievable'
- Guidance recognises you may be unable to quantify some uncertainties
 - Identify and describe these
- Quantify the overall impact of the uncertainties you are able to quantify
 - This will be *conditional* on your assumptions about the unquantified uncertainties
- Avoid language that implies quantitative judgements about the unquantified uncertainties (e.g. 'unlikely')





Context

- Chinese children affected by deliberate contamination of milk powder with melamine
- EFSA issued urgent advice in 2008:
 - Exposure of adults does not raise concern
 - Children with high consumption of chocolate and biscuits contaminated at the highest levels could potentially exceed TDI by over 3-fold
 - Currently unknown whether such high-level scenarios occur in EU





2008 statement based on calculations with varying assumptions for uncertain parameters

Melamine concentration	Dietary exposure in proportion of TDI			
	60 kg adult		20 kg child	
	Mean	95 th percentile	Mean	95 th percentile
Quality filled biscuit (16%)				
Median	0.3%	0.7%	1%	2%
High	30%	60%	90%	180%
Chocolate (25%)				
Median	0.3%	1%	1%	3%
High	30%	90%	90%	269%
Combined consumption				
Biscuit	30%		90%	
Chocolate		90%		269%
Combined	(120%	(359%
Biscuit		60%		180%
Chocolate	30%		90%	
Combined		90%		270%





Minimal application of Guidance

- List uncertainties affecting the assessment
 - Including realism of high estimates for consumption, % milk powder, concentration
- Quantify overall uncertainty for the three conclusions:
 - Probability highest adult exposure > TDI
 - Probability highest child exposure > TDI
 - Probability that the scenario occurs in EU





Minimal application of Guidance

- Assess probabilities by expert judgement
 - Observe principles of EFSA Guidance on elicitation of expert judgement
 - Consider using simplified scale for probabilities:

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

If unable to quantify, probability is unknown





Options for refinement (if needed)

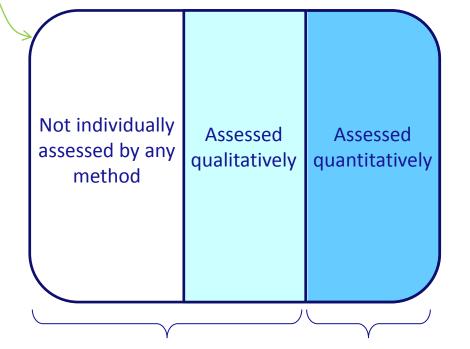
- Refine assessment for worst-case exposure
 - Quantify main uncertainties individually
 - with ranges (interval analysis)
 - with distributions (probabilistic)
- Reframe assessment to assess proportion of consumers exceeding TDI
 - Requires probabilistic treatment of variability
 - Quantify uncertainty about variability
 - with ranges or distributions
- Not necessary or feasible to quantify all uncertainties individually
 - Combine quantified+unquantified→overall





GENERAL APPROACH TO OVERALL UNCERTAINTY

Identified uncertainties



Quantify combined contribution by expert judgement

Individually quantified uncertainties

Flexibility:

- Refine analysis as far as needed
- Use whatever methods are suitable
- Elicit expert judgements formally or informally

Combine by calculation or expert judgement to assess overall uncertainty

address in longer term,

when revising procedures





STANDARD ASSESSMENT PROCEDURES

Panels to implement

Uncertainty Guidance

- Contain some provision for variability/uncertainty
 - E.g. assessment factors, default values, etc.
- When appropriate data available, there is no need for additional uncertainty analysis 😊 😊
- When data are limited, uncertainty analysis is needed
- However, also need to address uncertainty about the relation of standard procedures to actual risk

Uncertainty due to Uncertainty about limitations of available data relation to actual risk **Standard Available Standard Actual** assessment risk data data procedure **Practical starting point for** More challenging -





IMPLICATIONS FOR DECISION-MAKERS

- Increased dialogue between assessors and decision-makers
- More, clearer information on uncertainty
 - Range and likelihood of alternative outcomes
- Better information for decision-making
 - Choose options that increase the chance of positive outcomes
- More transparency in decision-making
 - As recommended by Heads of Food Agencies WG
- Some challenges for communication
 - EFSA working to develop a consistent strategy





NEXT STEPS

- Public consultation closes 10 Sept
- Revised draft for endorsement by SC
- Testing phase
 - Each Panel/Unit to do at least one example
 - Support from Uncertainty WG/AMU
 - Panel/Unit 'ambassadors' to lead implementation
 - Involve risk managers
 - Targetted consultation with stakeholders
- New training courses
 - Uncertainty and variability
 - Steering expert elicitation
 - E-module on probability judgements
- Final draft for adoption by Scientific Committee 19





THANK YOU!!!

- EFSA Scientific Committee
- Working Group on Uncertainty in Risk Assessment: Jan Alexander, Diane Benford, Peter Craig, Alessandro Di Domenico, Anthony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Ambroise Martin, Alicja Mortensen, Kaare Nielsen, Birgit Nørrung, Bernadette Ossendorp, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz and Detlef Wölfle
- EFSA staff members: Andrea Germini, Laura Martino, Caroline Merten, Olaf Mosbach-Schulz and Anthony Smith

Qualitative

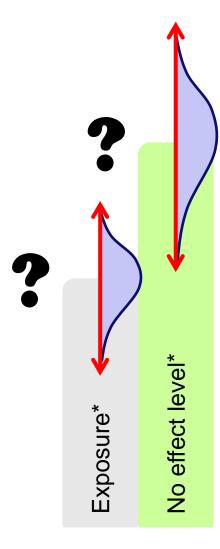
Descriptive:

- Source and nature of uncertainty
- Verbal expressions of magnitude and likelihood, e.g. 'negligible', 'likely'

Ordinal scales:

- Low/medium/high
- -/+ symbols
- Etc.

'Responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors' (Codex, 2013)



Quantitative

Range:

Range of possible outcomes

Probability:

- Range and probability of alternative outcomes
- Probability of adverse outcomes

Bounded probabilities:

- <1, <5, <10, <33%
- >50, >66, >90% etc.

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

'quantify as far as scientifically achievable' – Codex & SC 2009, also 2012

*Principles apply to any type of risk