EFSA's guidance on Uncertainty in scientific risk assessment

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Focal Points Meeting, 8 Feb 2018, Utrecht

efsa
European Food Safety Authority

UNCERTAINTY

«Uncertanty is an uncomfortable position.

But certainty is an absurd one»

Voltaire

Limitations in knowledge

Uncertainty versus variability

UNCERTAINTY AND VARIABILITY

- Uncertainty refers to our state of knowledge
- Variability is a property of the real world

- Uncertainty may be altered (either increased or decreased) by further research, but variability cannot
- Some types of variability can be altered by risk management actions (e.g. to change exposures)

WHAT DO WE MEAN BY 'UNCERTAINTY'?

- '~~limitations in knowledge~~'
- EFSA defines uncertainty as:
  - **"A general term referring to all types of limitations in available knowledge that affect the range and probability of possible answers to an assessment question"**

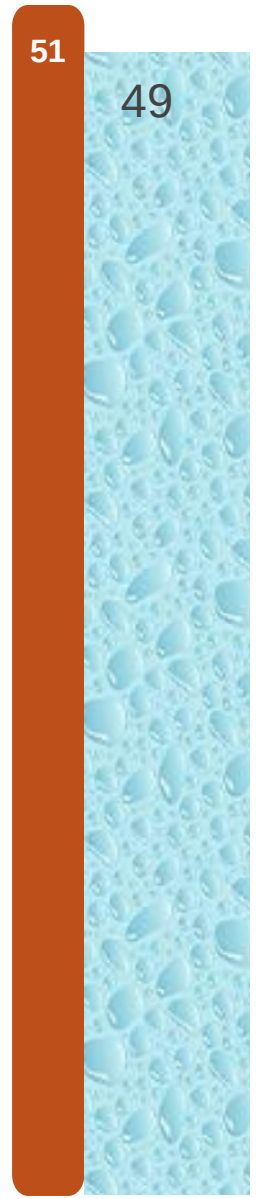
WHY DO WE NEED TO ADDRESS UNCERTAINTY?

- Recognised requirement in risk assessment
- Essential information for decision-making
- Critical for transparency, credibility and trust

Example 1: Red River

Red River Flood, Grand Forks USA, 1997

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



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)

Nate Silver, The Signal and the Noise, 2012

EXAMPLE 1: RED RIVER

Risk managers need to know:

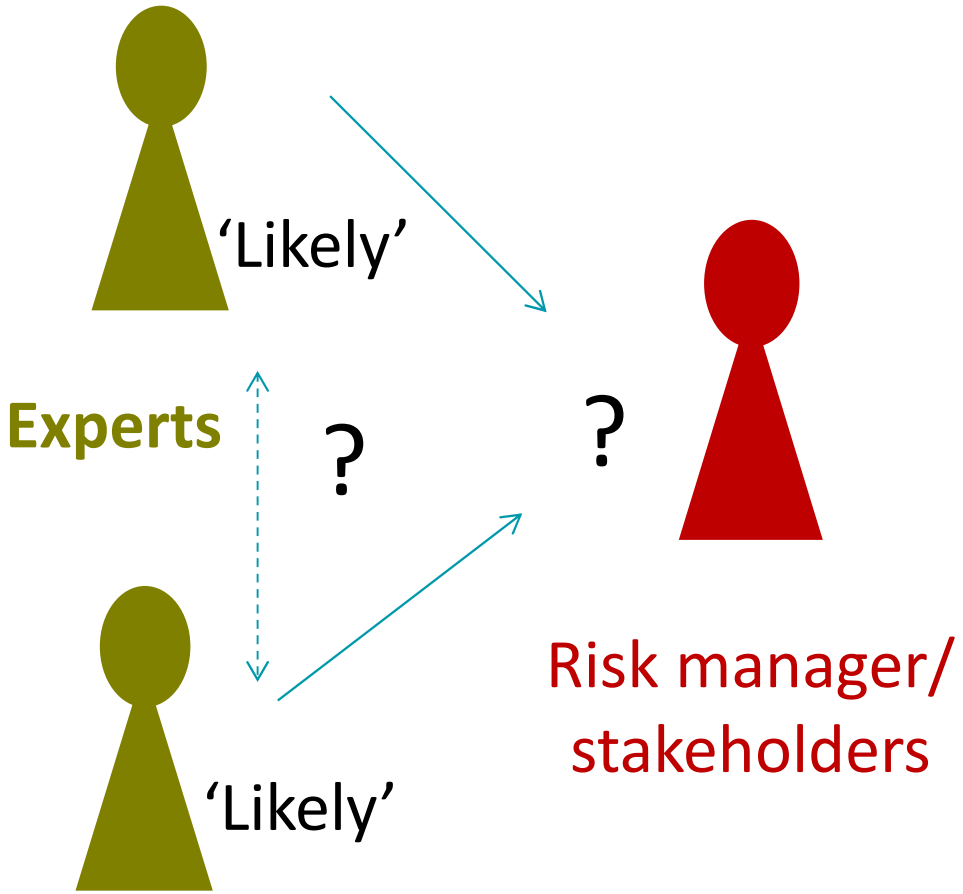
- **How much** higher might the river rise?
  - Quantitatively
  - Taking account of as much of the uncertainty as possible
- **How likely** is it to exceed the levee height?

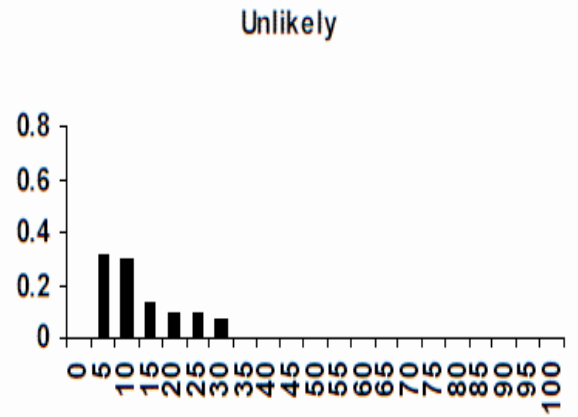
EXAMPLE 2: 'LIKELY'

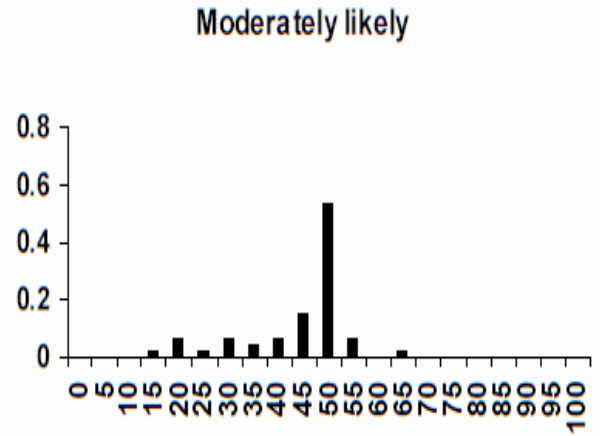
- **What probability do you associate with the word 'Likely'?**
- Write down your probability, expressed as a percentage between 0 and 100%

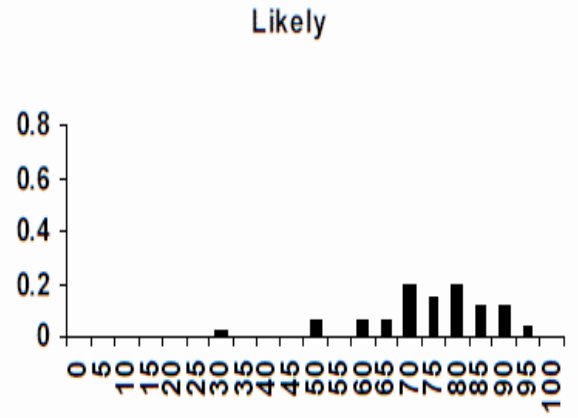
EXAMPLE 2: 'LIKELY'

- Words are ambiguous – mean different things to different people





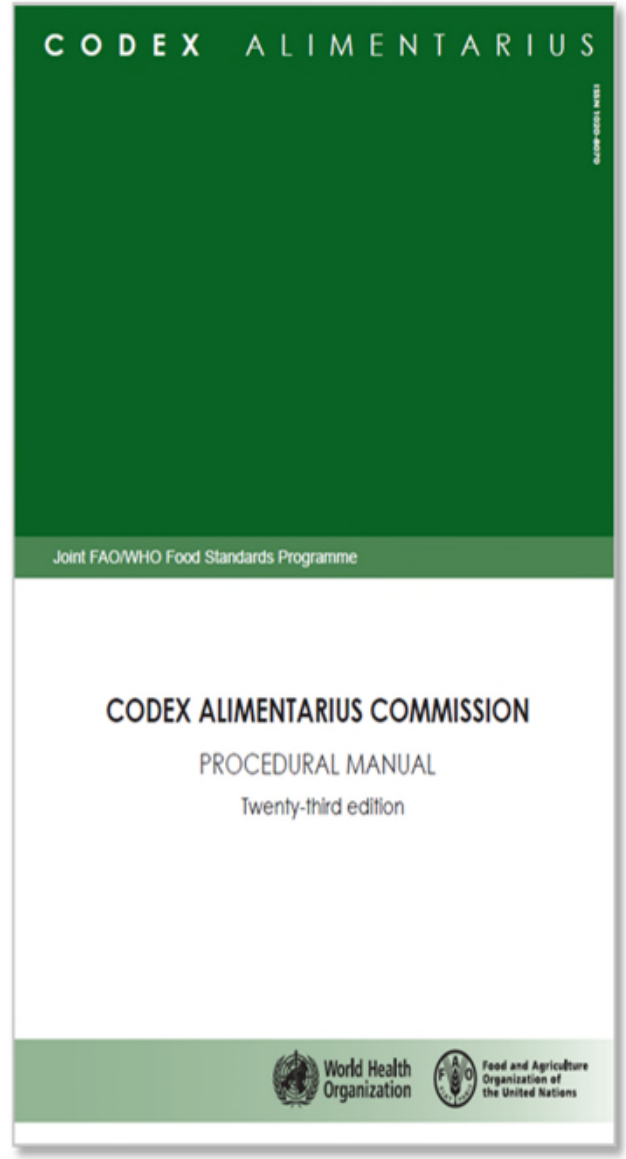




Macleod & Pietravalle

RECOGNISED REQUIREMENT IN RISK ASSESSMENT

- '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)

EFSA Journal

EDITORIAL

APPROVED: 26 March 2015

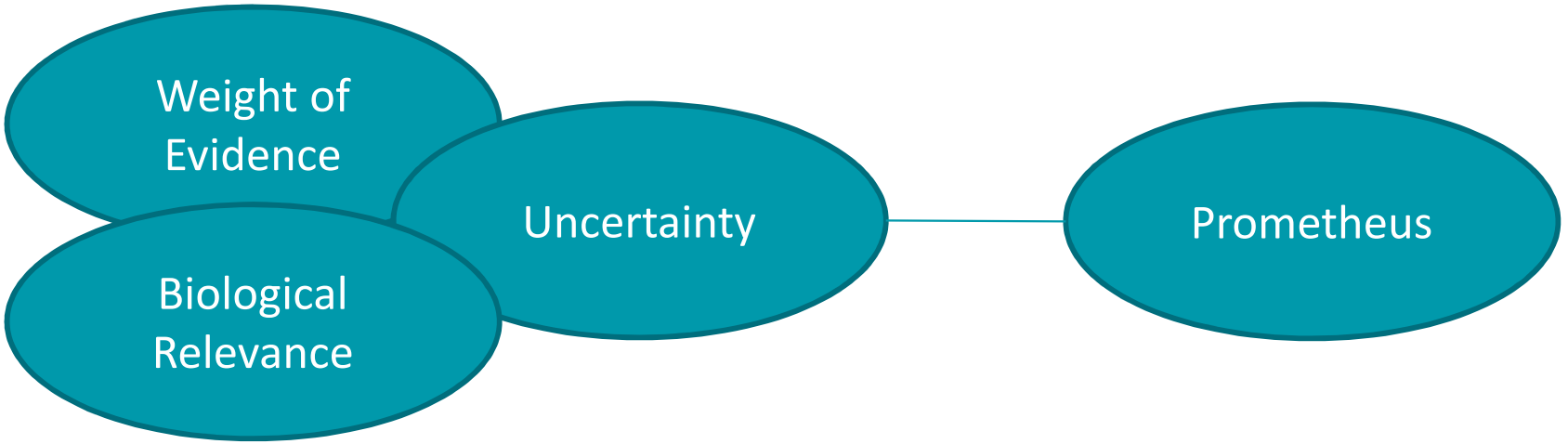
PUBLISHED: 27 March 2015

doi:10.2903/j.efsa.2015.e13031

Increasing robustness, transparency and openness of scientific assessments

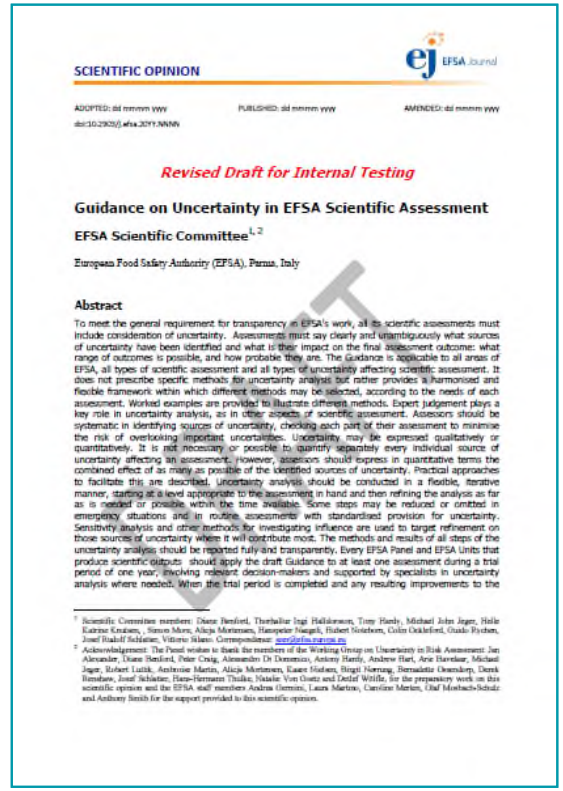
Hardy A, Dorne JLCM, Aiassa E, Alexander J, Bottex B, Chaudhry Q, Germini A, Nørrung B, Schlatter J, Verloo D, Robinson T

Scientific assessments are evidenced-based and demand rigorous methodologies to collect, evaluate and integrate scientific evidence, together with transparent and open communication of the processes



UNCERTAINTY GUIDANCE DEVELOPMENT

- GD Uncertainty development (2013-2017)
- **1st draft version** (June 2015)
- **Public consultation** (summer 2015)
- **Revised draft for internal testing published** (March 2016)
- **1 year Trial Period** (until May 2017)
- 4 **training sessions** in 2016
- **Impact analysis** after end of trial phase (March – May 2017)
- EFSA **workshop** (June 2017)



SCIENTIFIC OPINION

EFSA Journal

Revised Draft for Internal Testing

Guidance on Uncertainty in EFSA Scientific Assessment

EFSA Scientific Committee

European Food Safety Authority (EFSA), Parma, Italy

Abstract

UNCERTAINTY GUIDANCE DEVELOPMENT

- **Concise Guidance** on Uncertainty Analysis in Scientific Assessments (24 Jan 2018)
- **Supporting Opinion** on principles and methods

- **implementation** plan (with SANTE):
  - General risk assessment from mid 2018
  - Regulated products thereafter

- WG **communication** uncertainty (July 2017):
  - Q1 2018: 1st Draft guidance at SC
  - Q2 2018: public consultation
  - Q3 2018: Guidance on communicating uncertainty out

- Trainings, WG support, conferences, 2nd impact assessment (2021+),

EFSA Journal

GUIDANCE DOCUMENT

ADOPTED: 15 November 2017

doi: 10.2903/j.efsa.2018.5123

Guidance on Uncertainty Analysis in Scientific Assessments

EFSA Scientific Committee,
Diane Benford, Thorhallur Halldorsson, Michael John Jeger, Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Antonia Ricci, Guido Rychen, Josef R Schlatter, Vittorio Silano, Roland Solecki, Dominique Turck, Maged Younes, Peter Craig, Andrew Hart, Natalie Von Goetz, Kostas Koutsoumanis, Alicja Mortensen, Bernadette Ossendorp, Laura Martino, Caroline Merten, Olaf Mosbach-Schulz and Anthony Hardy

Abstract

GUIDANCE DOCUMENT – DIFFERENT ASSESSMENT TYPES

1. Introduction and scope
2. Types of scientific assessment
3. Uncertainty analysis for **standardised assessments**
4. Uncertainty analysis for **case-specific assessments**
5. Uncertainty analysis for **urgent assessments**
6. Uncertainty analysis when **developing or revising standardised procedures**
7. Dividing the assessment into parts
8. Ensuring questions and quantities of interest are well-defined
9. Identifying uncertainties
10. Prioritising uncertainties
11. Qualitative expression of uncertainty
12. Quantifying uncertainty using probability
13. Combining uncertainties for yes/no questions using a logic model
14. Combining uncertainties by calculation for a quantitative model involving only non-variable quantities
15. Combining uncertainties by calculation for a quantitative model involving variable quantities
16. Characterising overall uncertainty
17. Addressing uncertainty in conclusions and reporting

Separate guidance for different **types of assessment**

GUIDANCE DOCUMENT – ELEMENTS OF UNCERTAINTY ANALYSIS

1. Introduction and scope
2. Types of scientific assessment
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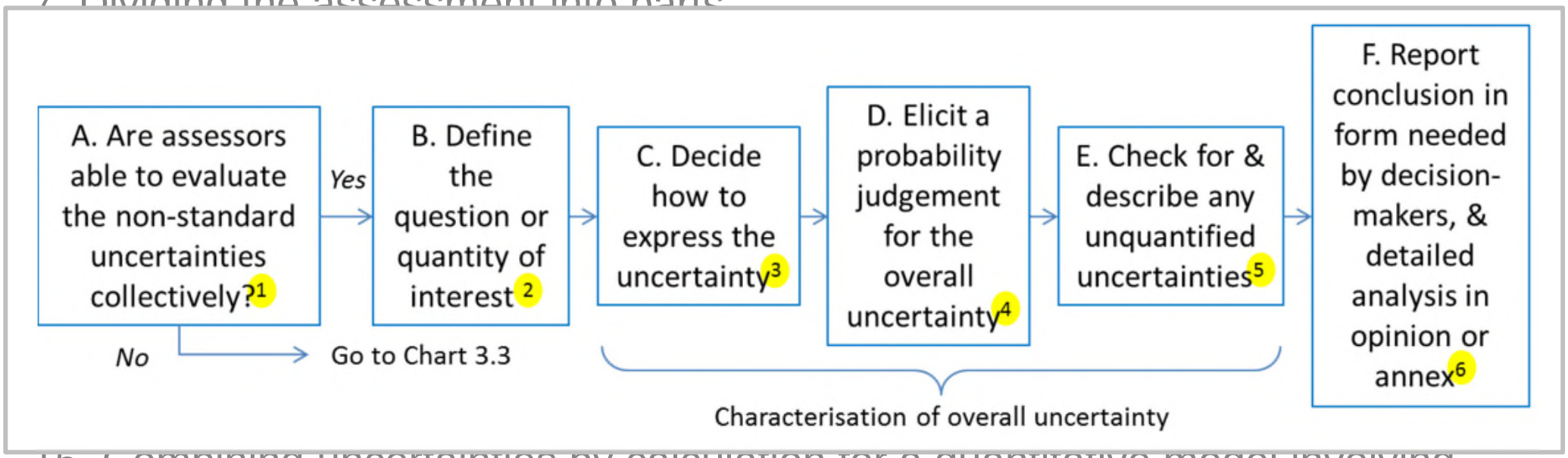
14. Combining uncertainties by calculation for a quantitative model involving only non-variable quantities
15. Combining uncertainties by calculation for a quantitative model involving variable quantities
16. Characterising overall uncertainty
17. Addressing uncertainty in conclusions and reporting

Separate section on each **element of uncertainty analysis**

GUIDANCE DOCUMENT – FLOWCHARTS

1. Introduction and scope
2. Types of scientific assessment
3. Uncertainty analysis for standardised assessments
4. Uncertainty analysis for case-specific assessments
5. Uncertainty analysis for urgent assessments
6. Uncertainty analysis when developing or revising standa
7. Dividing the assessment into parts

Each assessment section contains flow-charts with step-by-step guidance



15. Combining uncertainties by calculation for a quantitative model involving variable quantitie
16. Characterisin
17. Addressing u

Each flow-chart has footnotes providing brief practical guidance

GUIDANCE DOCUMENT – FOOTNOTES

1. Introduction and scope
2. Types of scientific assessment
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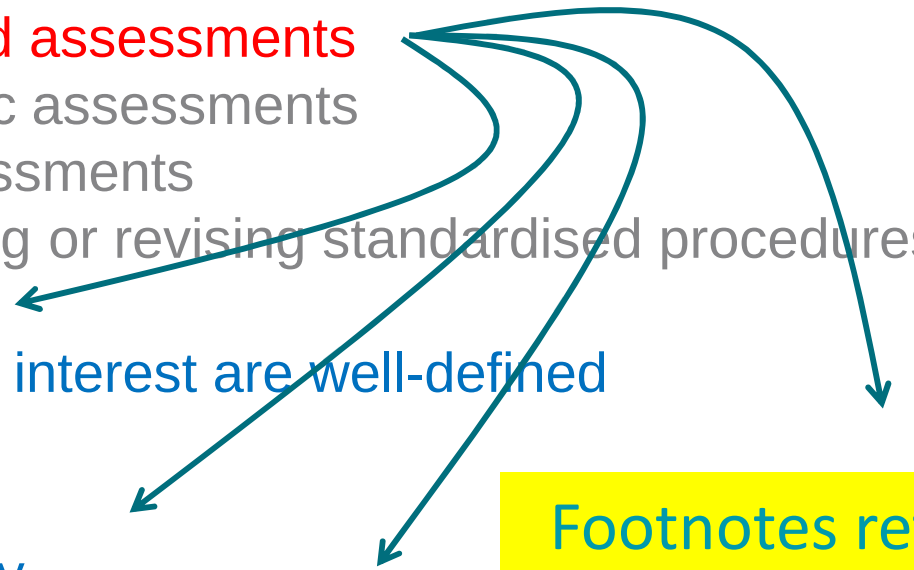
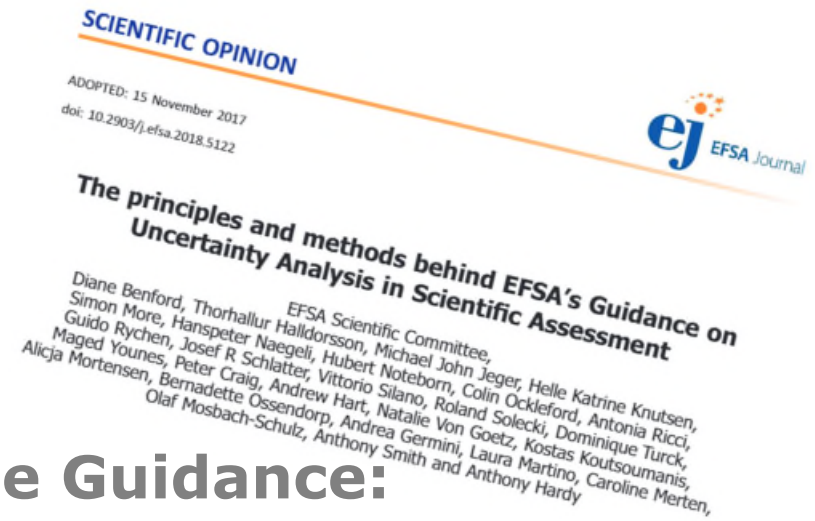


Footnotes refer reader to Sections 7-17 and/or Opinion where needed

SUPPORTING DOCUMENT


SCIENTIFIC OPINION

ADOPTED: 15 November 2017

doi: 10.2903/j.efsa.2018.5122

EFSA Journal

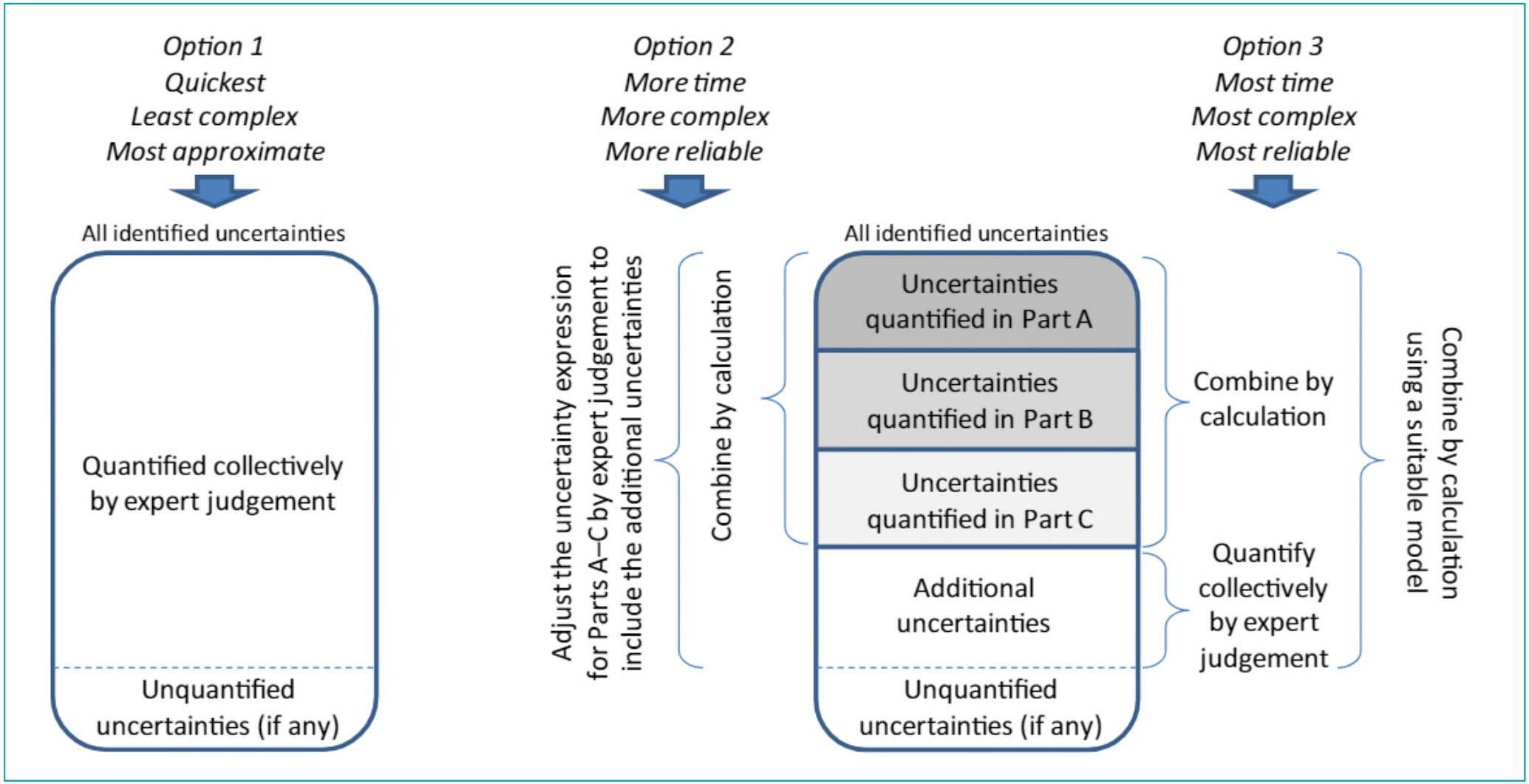
The principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment

EFSA Scientific Committee, Diane Benford, Thorhallur Halldorsson, Michael John Jeger, Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Antonia Ricci, Guido Rychen, Josef R Schlatter, Vittorio Silano, Roland Solecki, Dominique Turck, Maged Younes, Peter Craig, Andrew Hart, Natalie Von Goetz, Kostas Koutsoumanis, Alicja Mortensen, Bernadette Ossendorp, Andrea Germini, Laura Martino, Caroline Merten, Olaf Mosbach-Schulz, Anthony Smith and Anthony Hardy

Supporting information for the concise Guidance:

- Justify the approach taken
- Introduce and explain key concepts & principles for uncertainty analysis e.g:
  - Distinction between uncertainty & variability
  - Dependencies between sources of uncertainties
  - Evidence, weight of evidence, agreement, confidence and conservatism
  - Prioritisation of uncertainties
  - Expert judgements
- Review wide range of qualitative & quantitative methods (details in the 19 annexes)

OPTIONS FOR CHARACTERISING OVERALL UNCERTAINTY

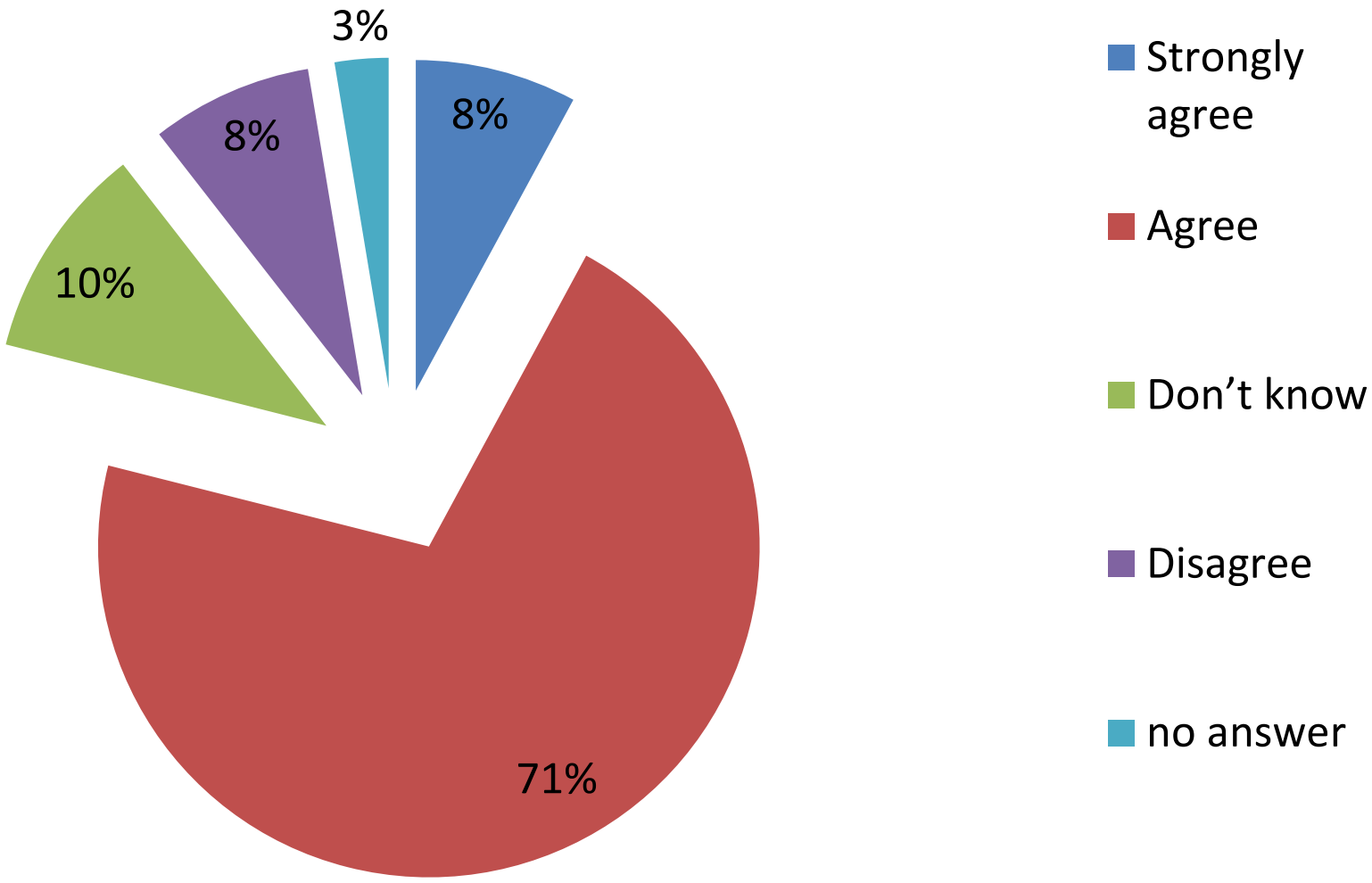


THE ROLE OF EXPERT JUDGEMENT

- Expert judgement is…
  - a vital component of all EFSA assessments
  - essential and unavoidable for assessing uncertainty
  - not guesswork!
  - careful, reasoned, evidence-based, transparent
  - subjective, and subject to psychological biases

- Formal methods have been developed to…
  - mitigate the impact of the psychological biases
  - take account of the available evidence
  - help experts reach well-founded judgements
  - make the process as objective & transparent as possible

IMPACT ASSESSMENT



APPLYING THE GUIDANCE IMPROVED TRANSPARENCY ABOUT UNCERTAINTY

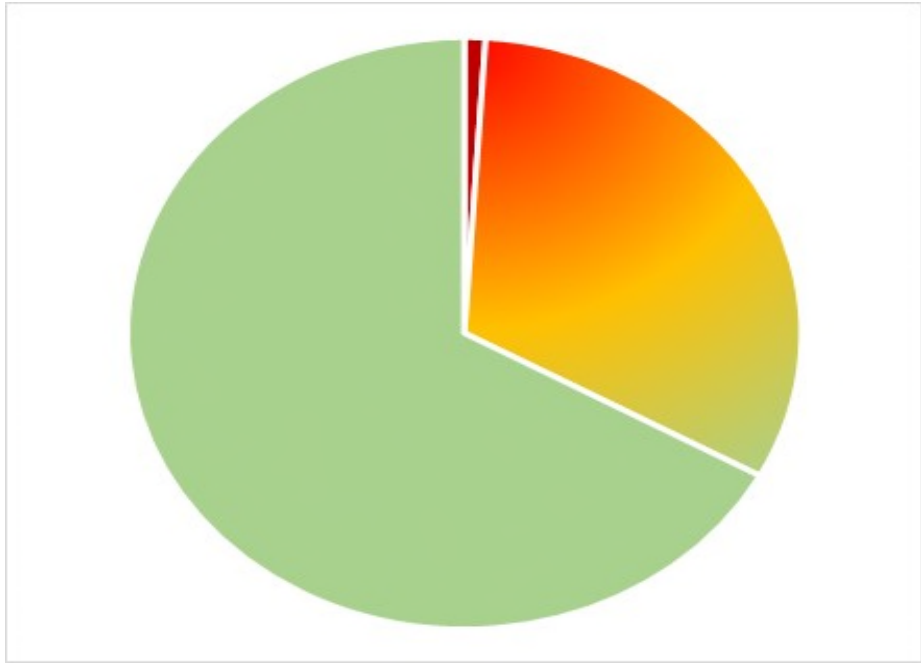
EXAMPLE: slaughtering pregnant animals

All pregnancies	P1	P25	median	P75	P99
Dairy cows	2%	9%	**16%**	27%	60%
Beef cattle	1%	7%	**11%**	18%	40%
Pigs	0%	3%	**6%**	9%	20%
Sheep	0%	5%	**10%**	14%	40%
Goats	0%	2%	**4%**	6%	10%

Estimated **prevalence** of mature female animals that are **pregnant** at the time of slaughter in Europe

Slaughtering pregnant animals:
A livestock fetus feels pain or other negative affect during stunning or bleeding of the dam.[1]

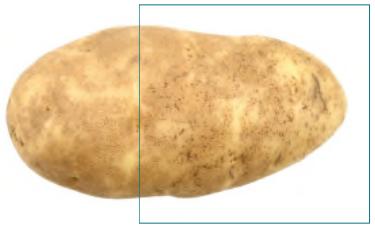
1% to 33% likely
66-99% unlikely

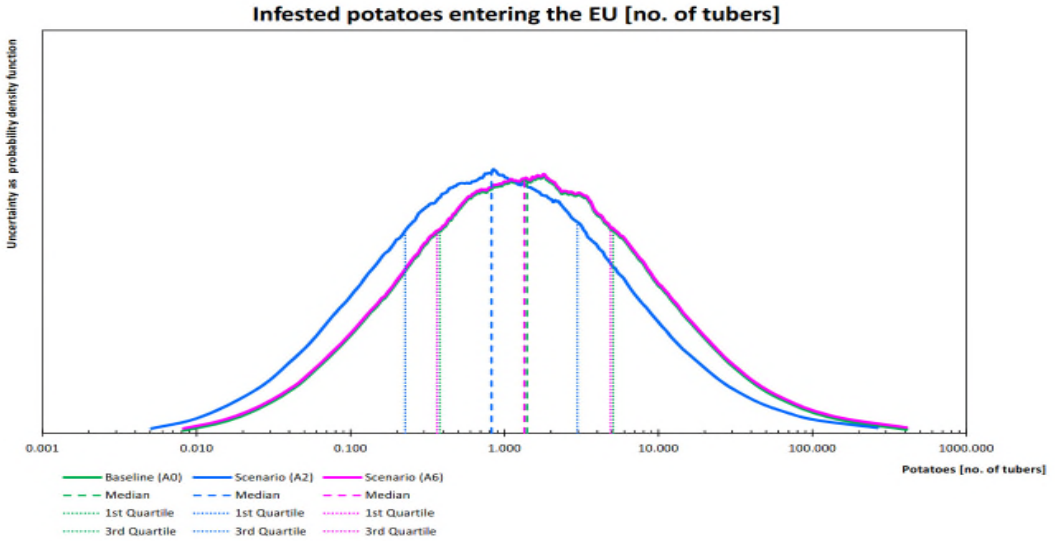


EXAMPLE: Entry of potato rot nematodes

Number of seed potatoes infested with the potato rot nematode imported into EU in the next year.[2]

1.3 with 50% uncertainty interval from 0.4 to 5 tubers per year



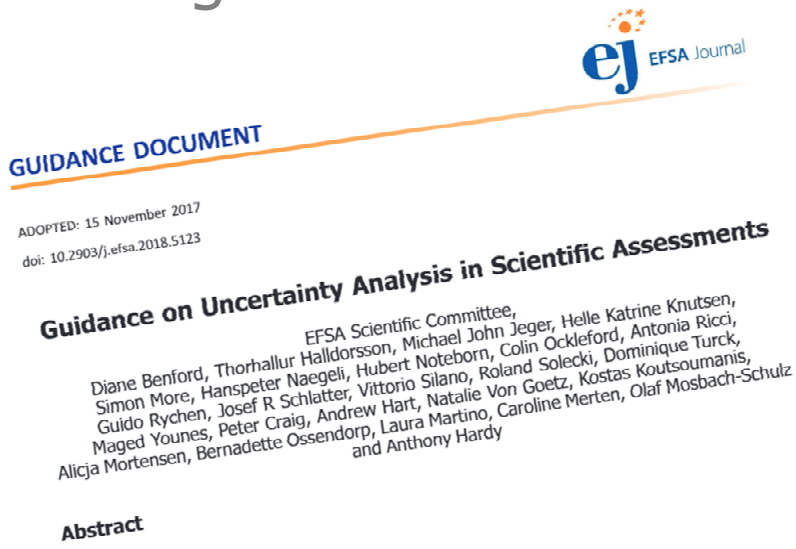


Mandatory

- Apply Guidance (2018 →)
- 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



EFSA Journal

GUIDANCE DOCUMENT

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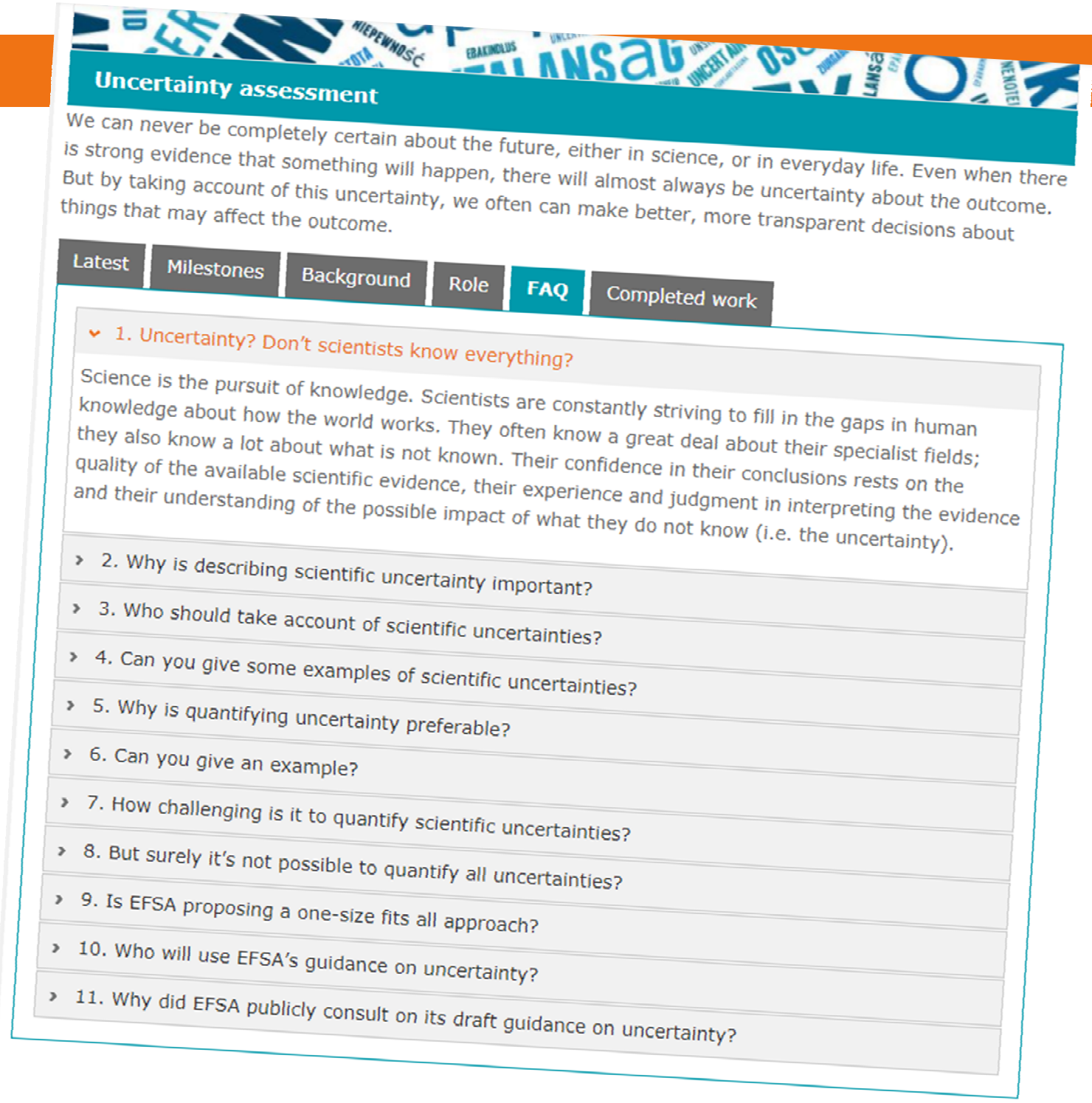
Abstract

Fit for purpose

FAQ'S



Uncertainty assessment

We can never be completely certain about the future, either in science, or in everyday life. Even when there is strong evidence that something will happen, there will almost always be uncertainty about the outcome. But by taking account of this uncertainty, we often can make better, more transparent decisions about things that may affect the outcome.

Latest | Milestones | Background | Role | **FAQ** | Completed work

- 1. Uncertainty? Don't scientists know everything?

  Science is the pursuit of knowledge. Scientists are constantly striving to fill in the gaps in human knowledge about how the world works. They often know a great deal about their specialist fields; they also know a lot about what is not known. Their confidence in their conclusions rests on the quality of the available scientific evidence, their experience and judgment in interpreting the evidence and their understanding of the possible impact of what they do not know (i.e. the uncertainty).

- 2. Why is describing scientific uncertainty important?
- 3. Who should take account of scientific uncertainties?
- 4. Can you give some examples of scientific uncertainties?
- 5. Why is quantifying uncertainty preferable?
- 6. Can you give an example?
- 7. How challenging is it to quantify scientific uncertainties?
- 8. But surely it's not possible to quantify all uncertainties?
- 9. Is EFSA proposing a one-size fits all approach?
- 10. Who will use EFSA's guidance on uncertainty?
- 11. Why did EFSA publicly consult on its draft guidance on uncertainty?

UNCERTAINTY IN RISK ASSESSMENT

Uncertainty? Don’t scientists know everything?

THANK YOU

"The important thing is to never stop questioning."

A. Einstein

"Uncertainty is an uncomfortable position. But certainty is an absurd one." Voltaire

"Exploring the unknown requires tolerating uncertainty."

B. Greene