The use of Expert Judgements in quantifying uncertainties in risk assessment of food and feed safety

— Experiences and lessons learnt from the implementation of EFSAs Expert Knowledge Elicitation Guidance —

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EFSA GUIDANCE ON EXPERT KNOWLEDGE ELICITATION

- Published 2014
- "A *systematic, documented and reviewable process* to retrieve expert judgements from a group of experts in the form of a probability distribution"
- Describes formal EFSA process for steering elicitation studies
- Contains standard protocols for Cooke, Sheffield and Delphi methods

European Food Safety Authority EFSA Journal 2014;12(6):3734

GUIDANCE OF EFSA

Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment[1]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Quantitative risk assessments facilitate the decisions of risk managers. In the EU, risk assessment in food and feed safety is the responsibility of the European Food Safety Authority (EFSA). Quantitative risk models should be informed by systematically reviewed scientific evidence, however, in practice empirical evidence is often limited: in such cases it is necessary to turn to expert judgement. Psychological research has shown that unaided expert judgement of the quantities required for risk modelling - and particularly the uncertainty associated with such judgements - is often biased, thus limiting its value. Accordingly methods have been developed for eliciting knowledge from experts in as unbiased a manner as possible. In 2012, a working group was established to develop guidance on expert knowledge elicitation appropriate to EFSA's remit. The resulting Guidance first presents expert knowledge elicitation as a process beginning with defining the risk assessment problem, moving through preparation for elicitation (e.g. selecting the experts and the method to be used) and the elicitation itself, culminating in documentation. Those responsible for managing each of these phases are identified. Next three detailed protocols for expert knowledge elicitation are given - that can be applied to real-life questions in food and feed safety - and the pros and cons of each of these protocols are examined. This is followed by principles for overcoming the major challenges to expert knowledge elicitation: framing the question; selecting the experts; eliciting uncertainty; aggregating the results of multiple experts; and documenting the process. The results of a web search on existing guidance documents on expert elicitation are then reported, along with case studies illustrating some of the protocols of the Guidance. Finally, recommendations are made in the areas of training, organisational changes, expert identification and management, and further developments of expert knowledge elicitation methodology within EFSA.

KEY WORDS

expert knowledge elicitation, Delphi, Sheffield method, Cooke's method, food safety, feed safety, risk assessment

[1] On request from EFSA, Question No EFSA-Q-2011-00850, approved on 5 July 2011.

[2] Correspondence: amu@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank the members of the Working Group on Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment: Fergus Bolger, Anca Hanea, Anthony O'Hagan, Jeremy Oakley, Gene Rowe and Meike Wentholt for the preparatory work on this scientific output and EFSA staff: Elisa Aiassa, Fulvio Barizzone, Eugen Christoph, Andrea Gervelmeyer, Olaf Mosbach-Schulz, Sara Tramontini for the support provided to this scientific output.

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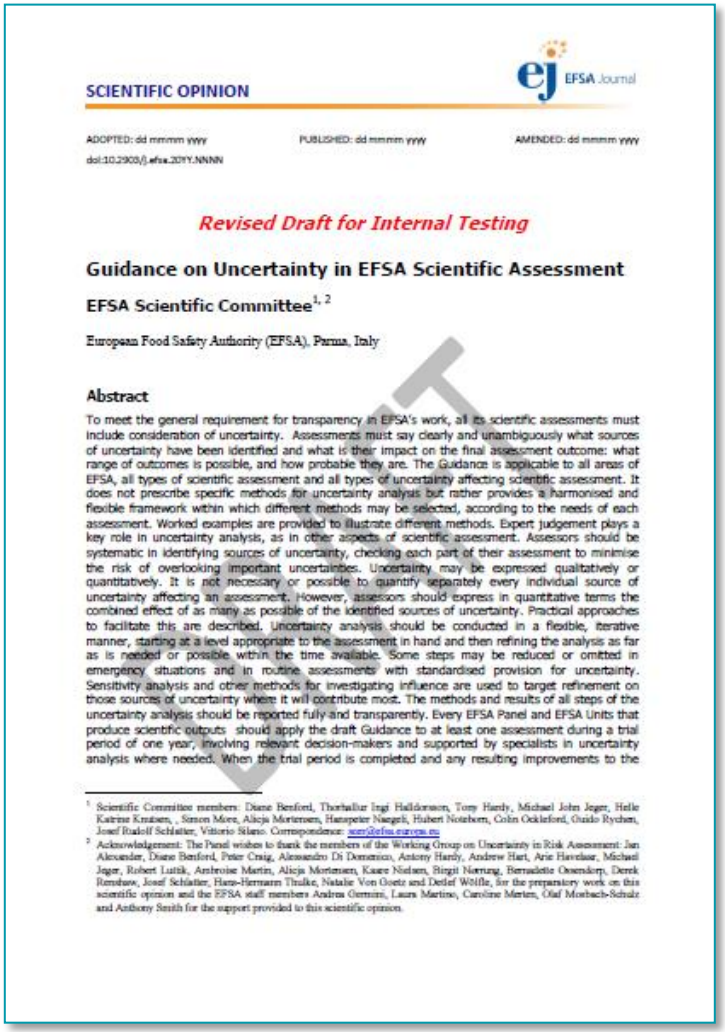
EFSA DRAFT GUIDANCE ON UNCERTAINTY

- Published March 2016
- Trial period of 1 year
- When finalised, will be mandatory for all EFSA's scientific assessments
- Central role for expert judgement
- Adds more streamlined methods:
  - 'Semi-formal EKE'
  - 'Expert discussion'
  - Approximate probability scale



SCIENTIFIC OPINION

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Revised Draft for Internal Testing

Guidance on Uncertainty in EFSA Scientific Assessment

EFSA Scientific Committee[1, 2]

European Food Safety Authority (EFSA), Parma, Italy

Abstract

To meet the general requirement for transparency in EFSA's work, all its scientific assessments must include consideration of uncertainty. Assessments must say clearly and unambiguously what sources of uncertainty have been identified and what is their impact on the final assessment outcome: what range of outcomes is possible, and how probable they are. The Guidance is applicable to all areas of EFSA, all types of scientific assessment and all types of uncertainty affecting scientific assessment. It does not prescribe specific methods for uncertainty analysis but rather provides a harmonised and flexible framework within which different methods may be selected, according to the needs of each assessment. Worked examples are provided to illustrate different methods. Expert judgement plays a key role in uncertainty analysis, as in other aspects of scientific assessment. Assessors should be systematic in identifying sources of uncertainty, checking each part of their assessment to minimise the risk of overlooking important uncertainties. Uncertainty may be expressed qualitatively or quantitatively. It is not necessary or possible to quantify separately every individual source of uncertainty affecting an assessment. However, assessors should express in quantitative terms the combined effect of as many as possible of the identified sources of uncertainty. Practical approaches to facilitate this are described. Uncertainty analysis should be conducted in a flexible, iterative manner, starting at a level appropriate to the assessment in hand and then refining the analysis as far as is needed or possible within the time available. Some steps may be reduced or omitted in emergency situations and in routine assessments with standardised provision for uncertainty. Sensitivity analysis and other methods for investigating influence are used to target refinement on those sources of uncertainty where it will contribute most. The methods and results of all steps of the uncertainty analysis should be reported fully and transparently. Every EFSA Panel and EFSA Units that produce scientific outputs should apply the draft Guidance to at least one assessment during a trial period of one year, involving relevant decision-makers and supported by specialists in uncertainty analysis where needed. When the trial period is completed and any resulting improvements to the

[1] Scientific Committee members: Diane Benford, Thorhallur Ingi Halldorsson, Tony Hardy, Michael John Jeger, Helle Katrine Knutsen, , Simon More, Alicja Mortensen, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Guido Rychen, Josef Rudolf Schlatter, Vittorio Silano. Correspondence: scm@efsa.europa.eu

[2] Acknowledgement: The Panel wishes to thank the members of the Working Group on Uncertainty in Risk Assessment: Jan Alexander, Diane Benford, Peter Craig, Alessandro Di Domenico, Antony Hardy, Andrew Hart, Arie Havelaar, Michael Jeger, Robert Luttik, Ambroise Martin, Alicja Mortensen, Kaare Nielsen, Birgit Nørrung, Bernadette Oosenbrug, Derek Renshaw, Josef Schlatter, Hans-Hermann Thulke, Natalie Von Goetz and Detlef Wölfle, for the preparatory work on this scientific opinion and the EFSA staff members Andrea Germini, Laura Martino, Caroline Merten, Olaf Mosbach-Schulz and Anthony Smith for the support provided to this scientific opinion.

Ref: https://www.efsa.europa.eu/en/topics/topic/uncertainty
https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf

BASIC PRINCIPLES OF UNCERTAINTY GUIDANCE

Mandatory:

- List identified uncertainties
- Characterise their combined impact on the assessment outcome
- Clear & unambiguous

Flexible:

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

Output required:

- Express in quantitative terms the combined effect of as many as possible of the identified sources of uncertainty
- …in terms of the range & probabilities of possible outcomes
- …and describe any uncertainties that cannot be quantified

COMBINED UNCERTAINTY

- We need to quantify the *combined* uncertainty
- *But* it is never possible to quantify *all* uncertainties individually
- Solution proposed in EFSA draft guidance:
  - quantify some uncertainties *individually*
  - quantify other uncertainties *collectively*
  - put them together to quantify *combined uncertainty*
  - *describe* any uncertainties that cannot be quantified

‘STANDARDISED ASSESSMENT PROCEDURES’

- Common in many parts of EFSA’s work – especially for assessment of regulated products
- Established in legislation or guidance documents
- Contain elements that are accepted by assessors and decision-makers as providing adequate cover for uncertainty
  - uncertainty factors, default values, conservative assumptions, etc.

- Uncertainty guidance approach:
  - Continue using existing procedures
  - Check for and assess ‘non-standard’ sources of uncertainty
  - Calibrate conservatism of the procedures when they come up for review

EXAMPLE - MYCOTOXINS IN FOOD

- EFSA Contaminants Panel (CONTAM Panel) opinion on T-2 and HT-2 toxins (EFSA, 2011) – *prior to draft uncertainty guidance*

- Standardised procedure for assess dietary risk to consumers
  - *Tolerable Daily Intake (TDI)* = lowest No Observed Adverse Effect Level from animal studies ÷ 100
  - *Exposure* = 95th percentile of specified population based on dietary surveys (consumption), concentration data and body weight
  - If Exposure ≤ TDI then conclude 'no health concern'

- For T-2 and HT-2:
  - *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

  - List of non-standard sources of uncertainty

MYCOTOXINS IN FOOD

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

- **Assessed collectively by expert judgement:**

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.

- **Implied quantitative judgements:**
  - ***>50% probability that risk is over-estimated***
  - ***the magnitude of the individual uncertainties and how they combine***

MYCOTOXINS IN FOOD

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- *Effect of other uncertainties*: >50% probability that risk is over-estimated

- **CONTAM Panel's overall conclusion is qualitative:**

> Estimates of chronic dietary exposure for populations of all age groups to the sum of T-2 and HT-2 toxins based on the available occurrence data are below the group TDI of 100 ng/kg b.w., and therefore there is no health concern.

- 'No concern' implies judgements about (a) the probability of exceeding the TDI, and (b) whether this raises concern
- **Need to *separate* these judgements & make them *transparent***

MAKING THE PROBABILITY JUDGEMENT TRANSPARENT

- *Tolerable Daily Intake (TDI)* = 100 ng/kg bw/day
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- *Implied measure of risk*: ratio of exposure to TDI

- Effect of other uncertainties: ***>50% probability that risk is over-estimated***

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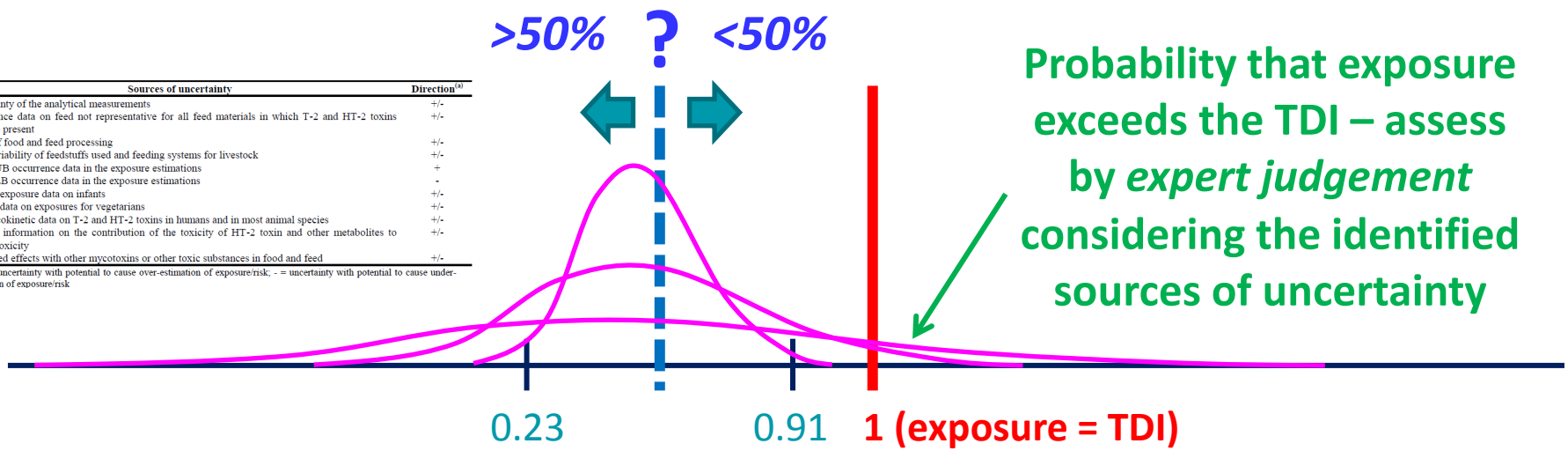

ELICITATION OF 'NON-STANDARD UNCERTAINTIES'

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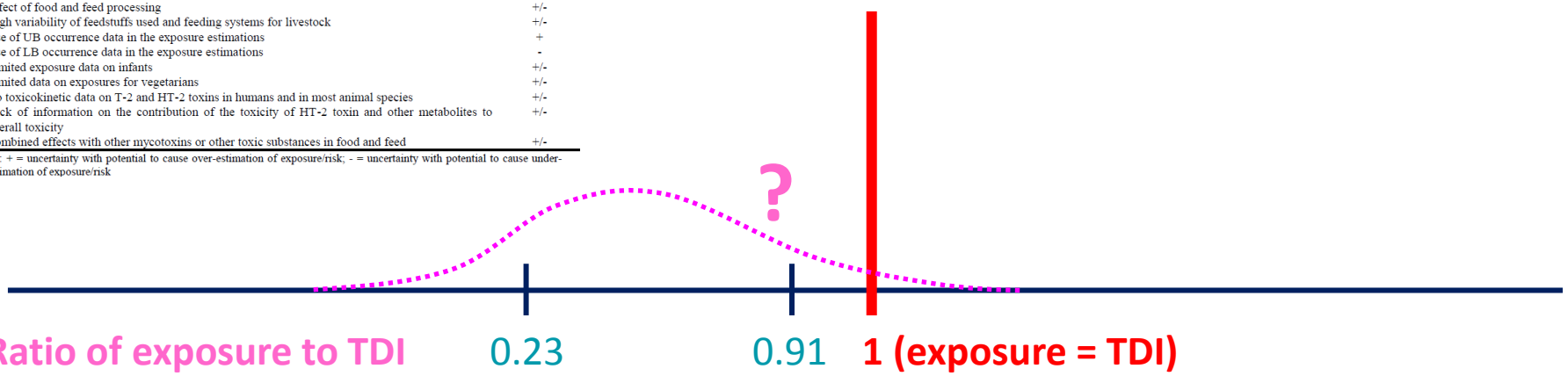

- *What would Exposure/TDI be if the uncertainties were resolved*?

- Contextual considerations for choice of elicitation method:
  - Strong time constraint, few experts per topic (≥1)
  - Assessed by Working Group, adopted by Panel
  - Non-overlapping areas of expertise
  - Conclusions reached by consensus

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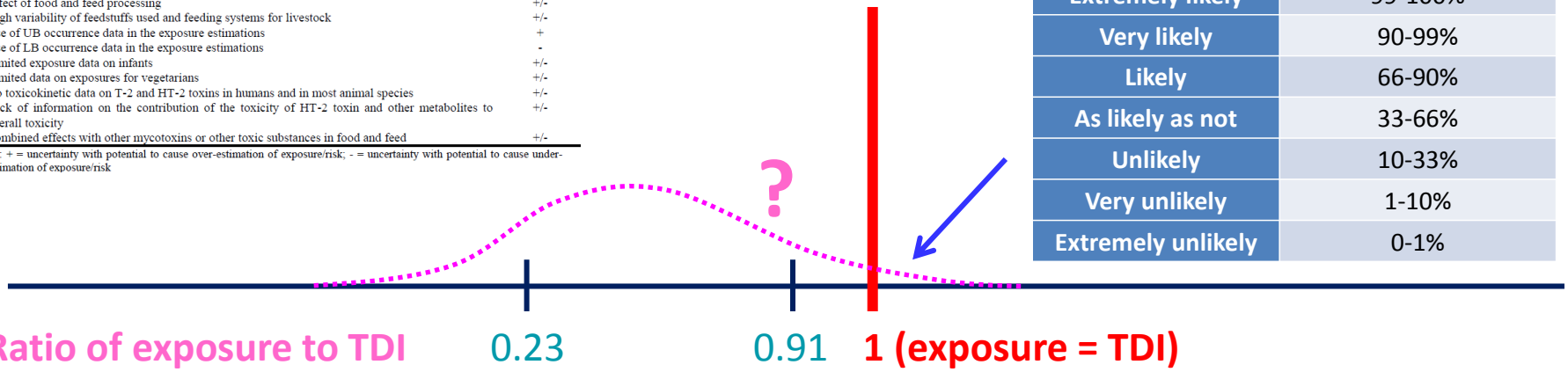


Probability term	Subjective probability range
Extremely likely	99-100%
Very likely	90-99%
Likely	66-90%
As likely as not	33-66%
Unlikely	10-33%
Very unlikely	1-10%
Extremely unlikely	0-1%

- Approaches explored in Trial Period:
  - 'Semi-formal' versions of Sheffield method (behavioural aggregation)
  - Elicit separate distributions for exposure and TDI
  - …or elicit one distribution for ratio of exposure to TDI
  - …or elicit probability for exposure > TDI
    - using 'approximate probability scale' adapted from IPCC

RESISTANCE TO QUANTIFYING UNCERTAINTY

- 'There are too many uncertainties'
- 'I cannot quantify them'
- 'I can quantify some, but not my model uncertainty'
- 'It would be subjective and that's unscientific'
- 'Uncertainty is unquantifiable by definition' (after Knight)
- 'You cannot quantify unknown unknowns'
- 'Quantifying uncertainty implies excessive precision'
- '…requires extensive data'
- '…requires complex computations'
- '…requires excessive time or resource'
- 'It takes too much time'
- 'The Panel won't accept it'
- 'Our job is to say whether it's safe, or not safe'
- 'Risk managers and the public don't want to know about uncertainty'
- 'Communicating uncertainty will undermine confidence'

SUGGESTIONS/ADVICE WELCOME…

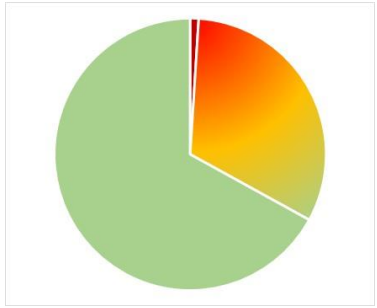
- What elicitation methods to apply in such cases?
- Any options for weighting/calibration of experts?

MORE APPLICATIONS

Judgements on Statements (true/false)

A lifestock fetus feels pain or other negative affect during stunning or bleeding of the dam.[1]

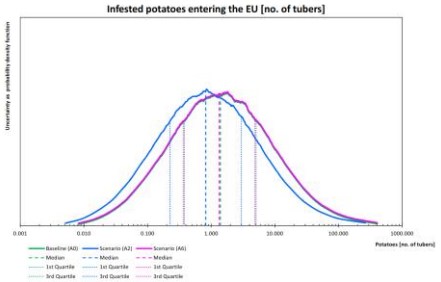
1% to 33% likely



Estimation of quantities (risks)

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

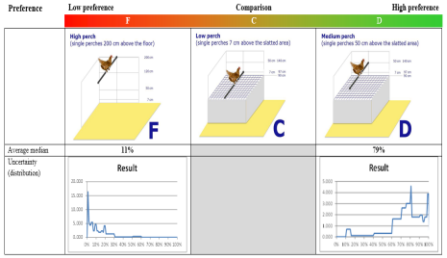
1.3 with 50% uncertainty interval from 0.4 to 5 tubers per year



Prioritise options (rankings)

Preference of laying hens to use a specific perch during nights. (out of 10 different perches)[3]

Preferred is a „single perch 50cm above the slatted area" (78% D vs C)



Ref: For details please refer to

[1] = EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare), 2017. Scientific Opinion on the animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). EFSA Journal 2017;15(5):4782, 96 pp

[2] = EFSA PLH Panel (EFSA Panel on Plant Health), 2016. Scientific opinion on the risk to plant health of Ditylenchus destructor for the EU territory. EFSA Journal 2016;14(12):4602, 124 pp.

[3] = EFSA AHAW Panel (EFSA Panel on Animal Health and Animal Welfare), 2015. Scientific Opinion on welfare aspects of the use of perches for laying hens. EFSA Journal 2015;13(6):4131, 70 pp

LESSONS LEARNT

- Framing questions in conceptual models
- Listing evidence and uncertainties
- Enable probabilistic judgements
- Combining quantified uncertainties
- Priority setting between essentials and full assessment
- Combined judgement on unquantified uncertainties

FRAMING THE QUESTIONS IN CONCEPTUAL MODELS

- Judgements should be **„in principle" observable** to the experts
- All terminology should be described **in an agreed glossary**
- The quantity to judge should be **an outcome of a „theoretical" experiment**
- The total risk assessment should be described **in a conceptual model**

LISTING EVIDENCE AND UNCERTAINTIES

- **All evidence is listed and summarized**, e.g. data sources and stats
- **Surrogates**, e.g. read-across, are actively searched
- **Limitations of all sources are discussed**, listed and qualitatively described (uncertainty table with direction, magnitude of bias)
- **Combination of evidence** by expert elicitation

ENABLE PROBABILISTIC JUDGEMENTS

- **Adapt the quantification method** to the problem:
  - Quantile ranges for numbers
  - Subjective belief for statements
  - Rankings for priorities
- Discuss **numerical representation versus precision**
- Select and **train one method** per quantification
- Combine **individual judgements with reasoning**, even when the latter is imperfect
- **Provide graphical feedback** to the experts

COMBINING QUANTIFIED UNCERTAINTIES

- A **mathematical formulation** of the conceptual model is preferable

- A **stepwise interpretation** of the conceptual model is helpful:
  - E.g. to get European estimates:
    1st step: Individual observations
    2nd step: Country specific estimates
    3rd step: European estimates

- A **combined judgement** is always possible

FIT FOR PURPOSE MODELLING

- Model screening enables to **select influencing factors**
  - E.g. Fast track estimates

- **Sensitivity analysis** is an important feedback to understand uncertainties and mitigation measures (e.g. for decision making)

- **Tiered approaches** are helpful:
  - Full formal procedure
  - Semi-formal procedure
  - Essentials

UNQUANTIFIED UNCERTAINTIES

Nevertheless not all uncertainties are individually assessable!

- List and discuss **all unquantified uncertainties**
- **Allow a correction of the final estimate** in view of the additional uncertainties

THANKS FOR YOUR ATTENTION

(Detail of the Nordic Pavilion by Terike Haapoja at 55th Venice Biennale, 2013, photograph by Olaf Mosbach-Schulz)

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