Recent activities of EFSA's Scientific Committee

Tony Hardy
Chair of the Scientific Committee

Advisory Forum, Utrecht, 6th February 2018

efsa
European Food Safety Authority

Role and responsibilities of the SC

- General coordination necessary to ensure the *consistency* of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods
- Opinions on *multisectoral issues* falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels
- It ensures the appropriate coordination between the work programme of EFSA's Scientific Panels to avoid the risk for the adoption of divergent scientific opinions
- It draws attention to any specific or *emerging issue* falling within its remit.

EFSA'S WORK ON RA METHODOLOGY

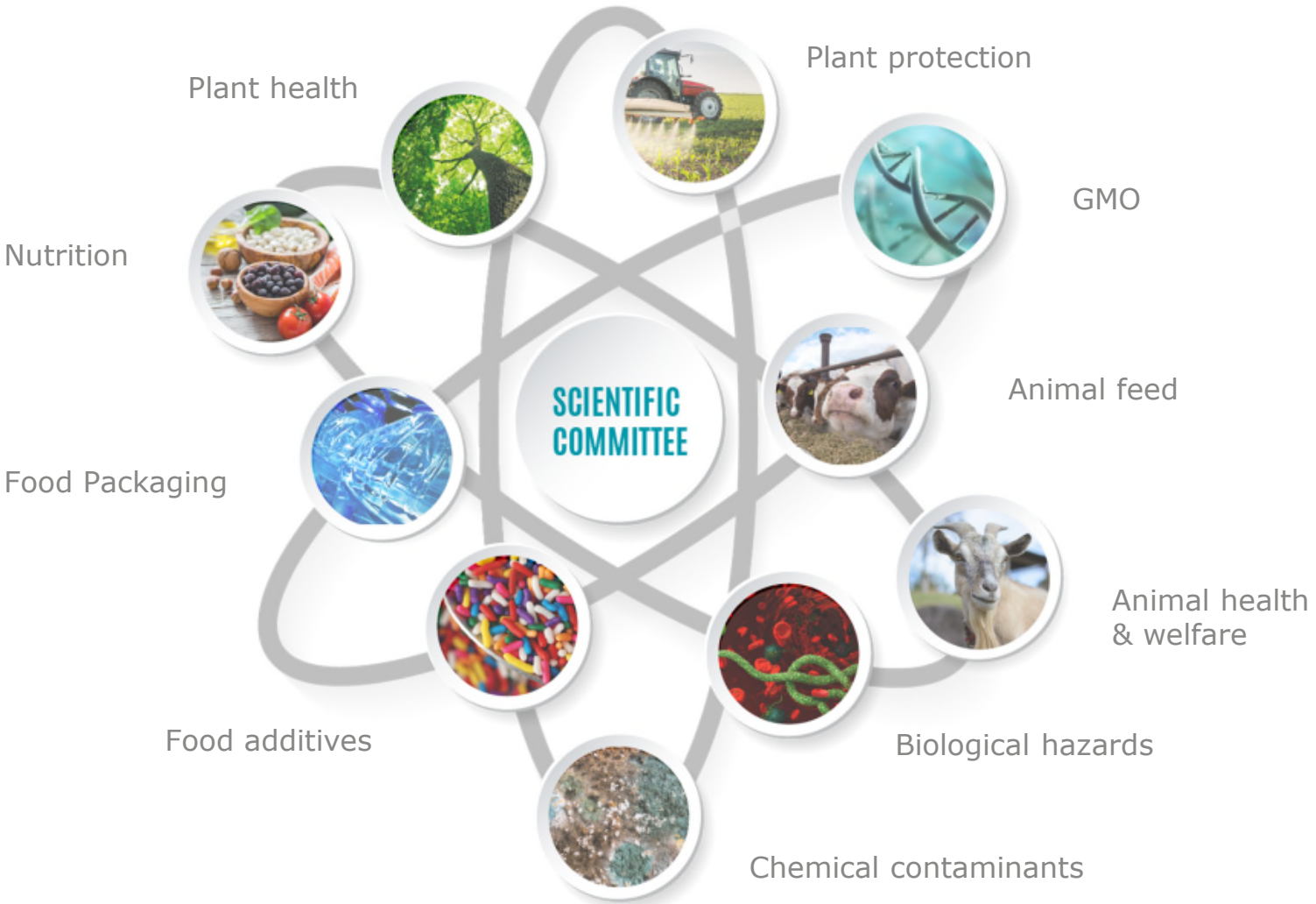
AIMS

- To identify best practices
- To assess the validity and utility of new RA methods
- To encourage harmonisation of methodology across EFSA's Scientific Panels

BENEFITS

- Ensuring EFSA is using the best available tools
- More consistent advice and decisions
- Better understanding and confidence in the way EFSA works

THE SCIENTIFIC PANELS AND SCIENTIFIC COMMITTEE



RISK ASSESSMENT METHODOLOGY (GENERIC)

SCIENTIFIC ASSESSMENT METHODOLOGIES

The three key elements of the scientific assessments

Weight of Evidence

Biological Relevance

Uncertainty Analysis

Guidance on the weight of evidence in scientific assessment

Weight of evidence is a measure of evidence on one side of an issue as compared with the evidence on the other side of the issue, or to measure the evidence on multiple issues.

WEIGHT OF EVIDENCE

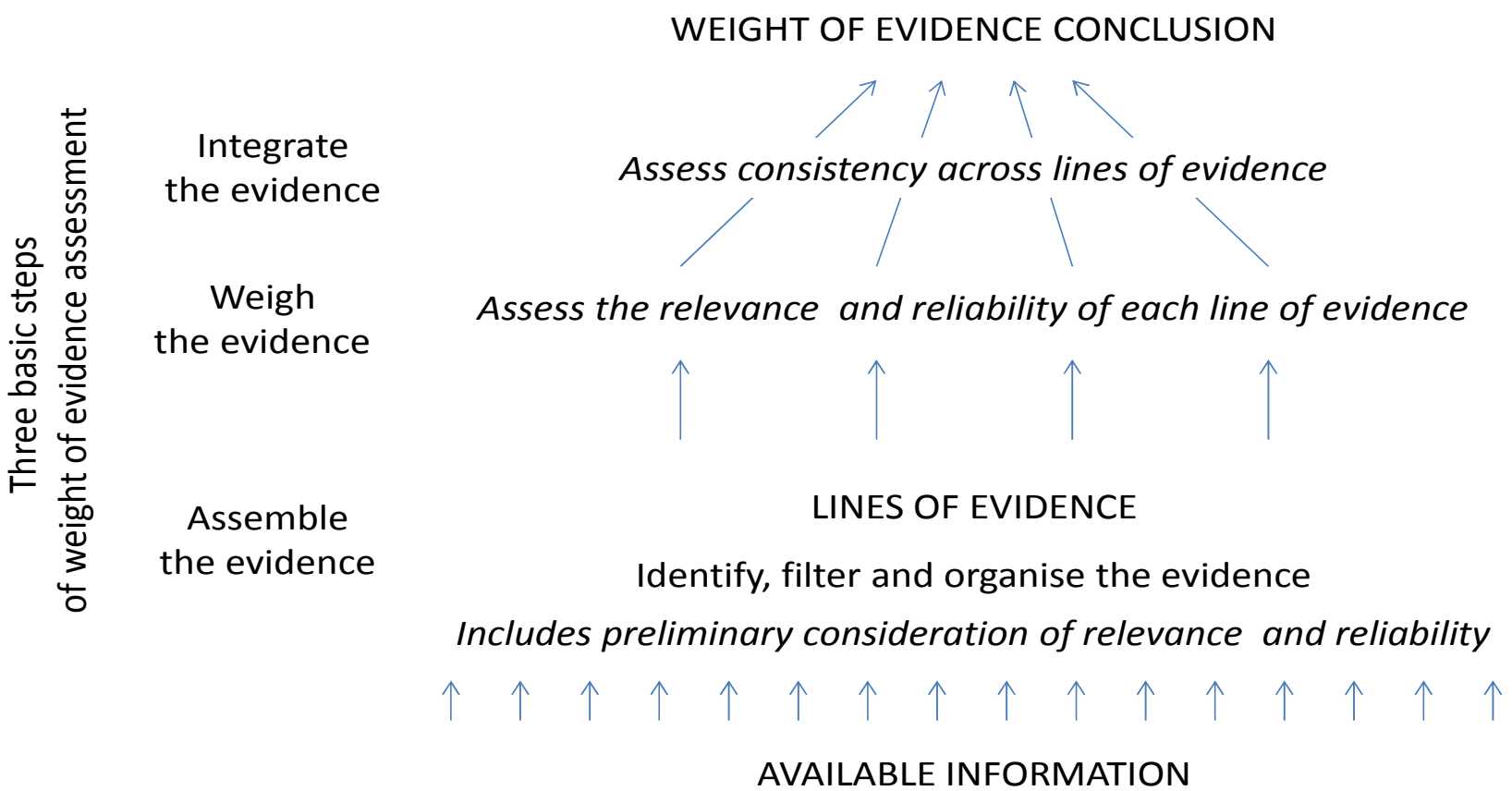
Content of the guidance

- Introduction
- General framework and principles for WoE assessment
- Overview of qualitative and quantitative methods for WoE assessment
- Practical guidance for conducting WoE assessment
- Reporting WoE assessment
- Annexes

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971/full

WEIGHT OF EVIDENCE

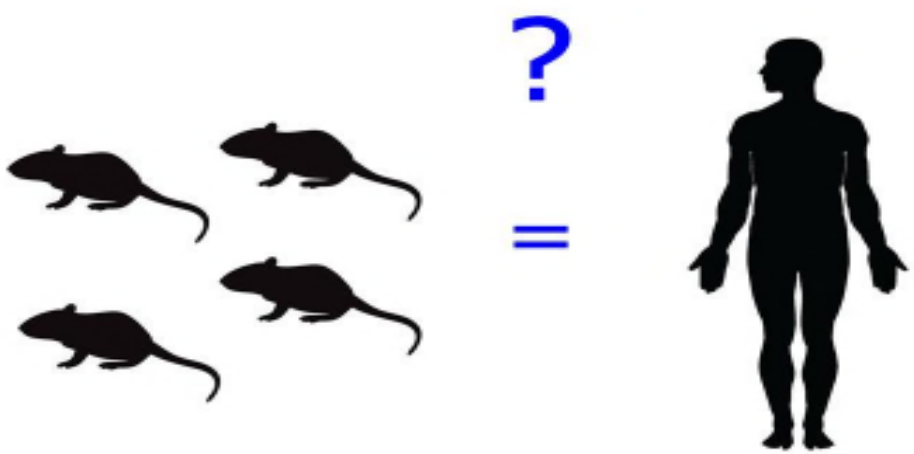
Relationship of relevance, reliability and consistency to the three basic steps of WoE assessment and to the conclusion for a WoE question



BIOLOGICAL RELEVANCE

Objective:

To prepare a Guidance for providing generic issues and criteria to consider biological relevance in relation to evidence used in scientific assessments



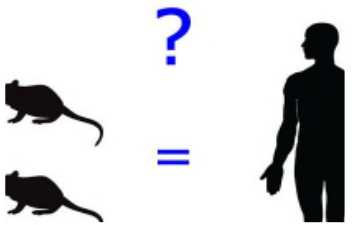
GUIDANCE ON BIOLOGICAL RELEVANCE

- Provides generic issues and criteria when considering whether an observed effect is of biological relevance (i.e. adverse [or positive health effect])

- Clarifies definitions and concepts including responses of a biological system to exposure, mode of action and adverse outcome pathways, thresholds, critical effect, modelling approaches and biomarkers

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4970/full

GUIDANCE ON BIOLOGICAL RELEVANCE

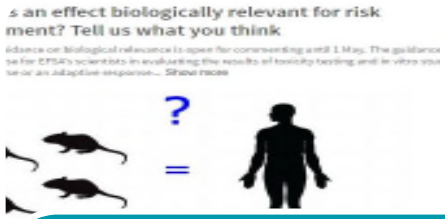


Assessment strategy

- Specification of the agents
- Specification of the subjects
- Specification of the effects
- Specification of the conditions

Collection and extraction of data

i.e. identification of potentially biologically relevant evidence/data as specified in the Assessment strategy



Appraisal and integration of the relevance of:

- the agents
- the subjects
- the effects
- the conditions

Uncertainty

WHAT DO WE MEAN BY 'UNCERTAINTY'?

- Often defined in terms of 'limitations in knowledge'

- SC Guidance defines uncertainty as:
  - "**all types of limitations in the knowledge available to the assessors at the time an assessment is conducted and within the time and resources agreed for the assessment**"

Why do we need to assess uncertainty?

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

TERMS OF REFERENCE WG UNCERTAINTY

- Develop guidance on how to characterise, document and explain uncertainties in the various steps of risk assessment (includes communication aspects)
- Develop a harmonised framework applicable to all relevant working areas of EFSA
- Demonstrate applicability with case studies
- Consider existing work by EFSA and other organisations

UNCERTAINTY GUIDANCE

Guidance Document on Uncertainty analysis in scientific assessment

- Concise, step by step guidance, flexible, scalable

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

- Supporting document, text book, toolbox

NEXT STEPS

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

TIMELINE OF EFSA'S GD ON UNCERTAINTY

- International Workshop Brussels (2013)
- Editorial and consultation on TORs (2013)
- **1st draft version** in June 2015
- **Public consultation** in summer 2015
- **Revised draft** in March 2016
- **Trial Period** of 1 year (until May 2017)
- To support the testing phase 4 **training sessions** were organised in 2016
- **Internal workshop** (June 2017)
- **Revised GD** and Opinion adopted (November 2017)
- **Published** (January 2018)
- Parallel **communication research** activities on uncertainty (2016 – 2018)
- GD on Communication (target September 2018)


GUIDANCE DOCUMENT

EFSA Journal

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


SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 15 November 2017

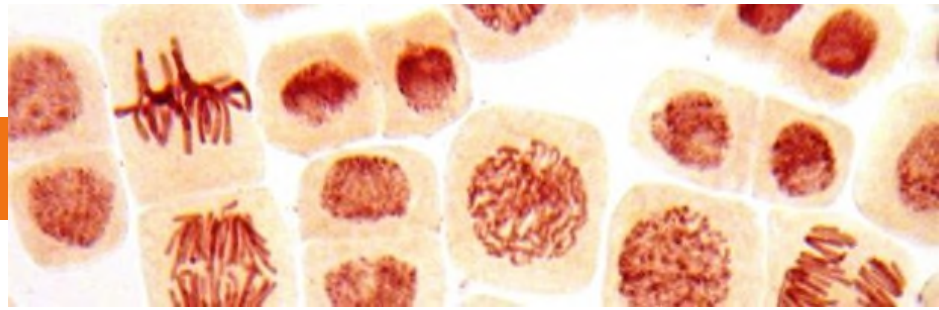
doi: 10.2903/j.efsa.2018.5122

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

Ref: https://www.efsa.europa.eu/en/topics/topic/uncertainty
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5123/full
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5122/full

GENOTOXICITY ADVICE



Opinion on genotoxicity assessment

- Adequacy of a historical assay used to follow up *in vitro* positive results in gene mutation tests
- Adequacy of demonstrating target tissue exposure in *in vivo* tests
- The use of data in a weight-of-evidence approach to conclude on the genotoxic potential of substances and the consequent setting of health-based reference values for use in human health risk assessment

- http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5113/epdf

GUIDANCE ON MIXTURES

- Guidance on Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals

- The guidance should be an overarching document aimed at the work of the EFSA Panels and relevant to scientific advisory bodies dealing with chemical risk assessment both within and across regulatory applications and sectors

- The guidance should address dose-addition, response addition, interactions, component-based and whole mixture approaches.

(Ongoing)

TIMELINE FOR GD MIXTURES

- **November 2016:** public consultation on terms of reference
- **November 2017:** Draft GD to EFSA SC
- **February 2018**: Second draft GD to EFSA SC
- **May 2018:** Endorsement by SC for public consultation
- **June – July 2018**: Public Consultation of the draft GD
- **December 2018**: Adoption of the draft GD
- **Spring 2019:** International workshop

RISK ASSESSMENT METHODOLOGY (SPECIFIC)

RA OF SUBSTANCES IN FOOD INTENDED FOR INFANTS <16 WKS

- Takes account of exposure assessment based on infant formula as the only source of nutrition, knowledge of organ development, overall tox profile, relevance of animal models to human development
- Public Consultation ended 31st March 2017
- Adopted by SC (April 2017) and published 2017

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4849/full

GD ON NANOMATERIALS

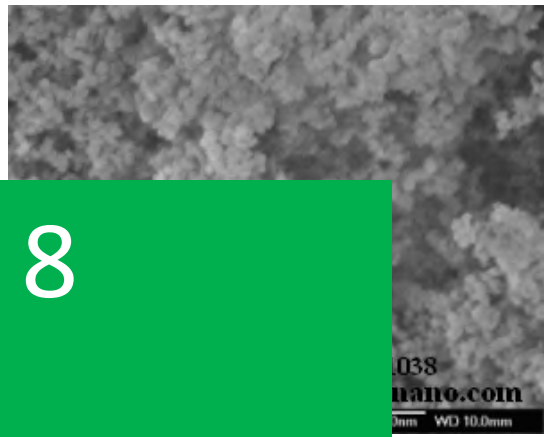
- **Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1 on human and animal health**

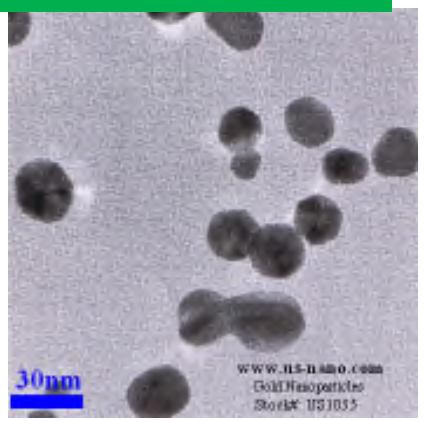
DRAFT GUIDANCE ON NANOMATERIALS

- Revision of EFSA Guidance 2011
- Criteria Novel Food Regulation (EU 2015/2283)
- Part 1 – human and animal health
- Pa
- 6

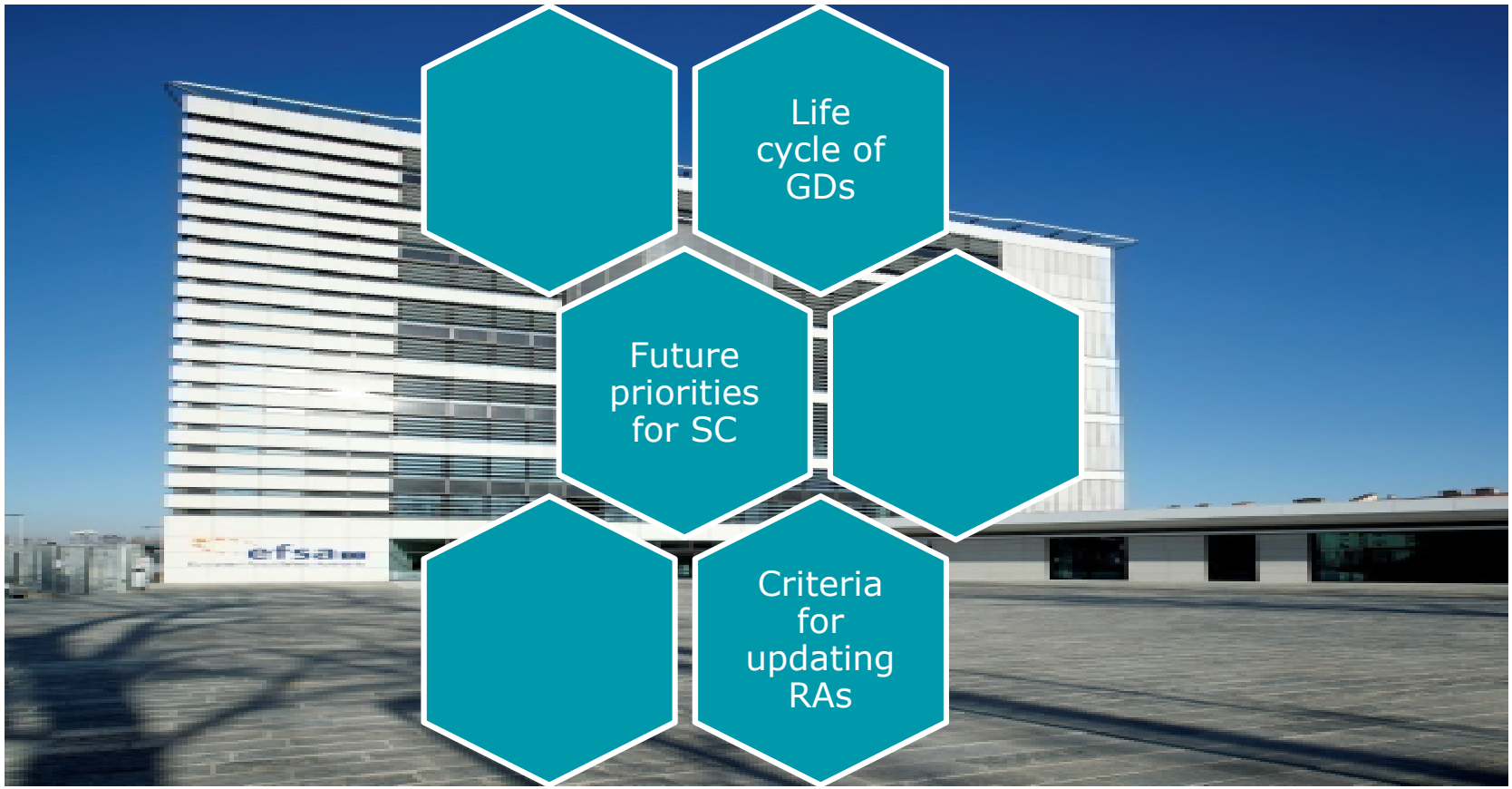
Public Consultation (finishes 8 March 2018)

- Novel foods
- Food additives
- Food Contact Materials
- Feed
- Nanopesticides
- Nanocarriers

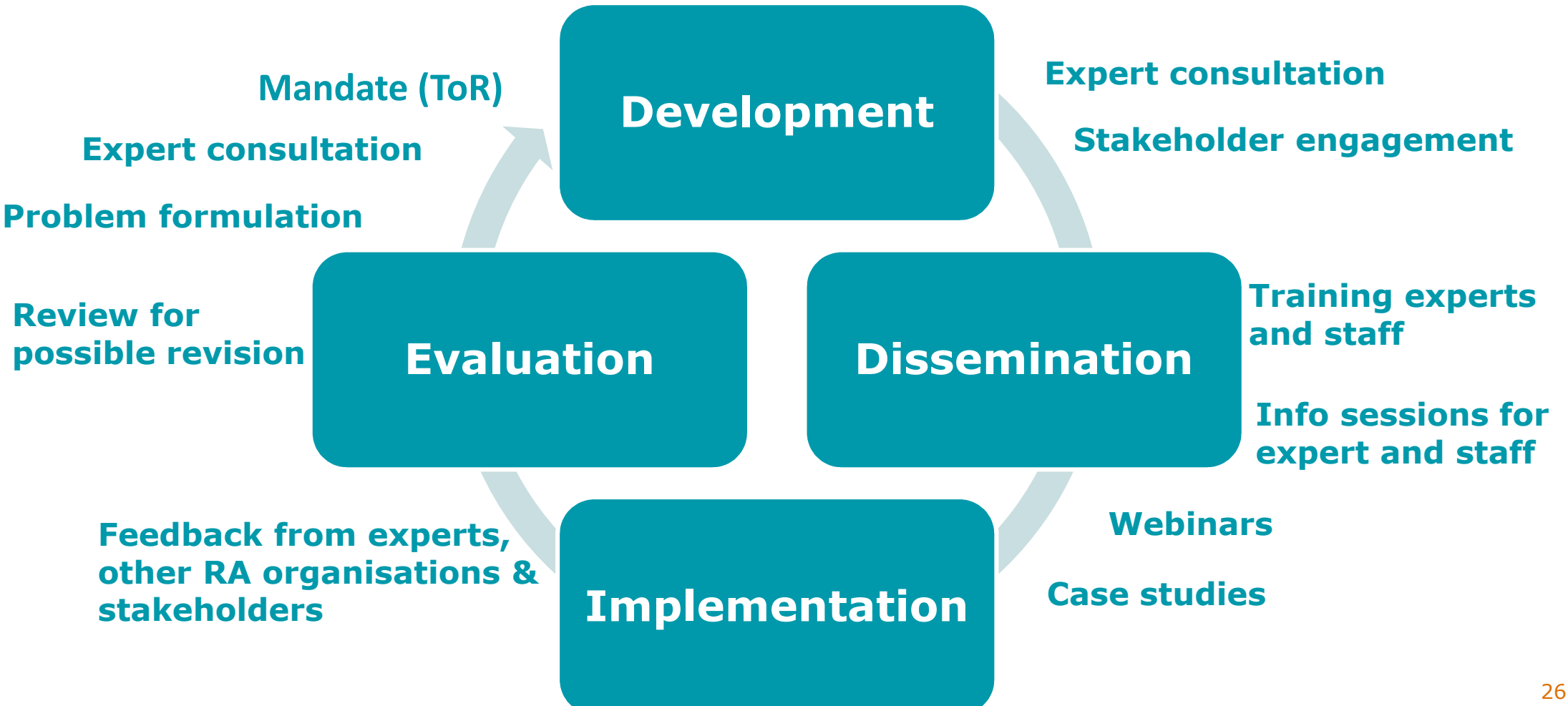




PROCEDURAL GUIDANCE



LIFE-CYCLE OF GUIDANCE DOCUMENTS



GUIDANCE ON LIFECYCLE OF EFSA'S CROSS-CUTTING GD (EFSA 2015)

EFSA requested SC to prepare a guidance that describes how SC and EFSA's cross-cutting guidance documents (GDs) should be used, reviewed and kept up to date.

- Data
  - SC GDs and general cross-cutting EFSA guidance were selected and used for the analysis.
  - Panel specific guidance were excluded from the evaluation
- Methodologies

23 GDs considered, for each identification of:

- Target audience (EFSA panels, applicants etc..)
- Level of obligation to follow (unconditional MUST or conditional – SHOULD)
- Current status (obsolete; in use; in use and revision on-going; possible revision envisaged)

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4080/epdf

Criteria to update a guidance

- New relevant, reliable and consistent information become available
- New legislation
- Upon request from Commission or MSs
- Mistakes or ambiguity identified

Prioritisation criteria to update/review

- When the GD is classified "unconditional" revision is considered a priority
- Number of EFSA panels for which GD is relevant
- If the guidance has direct and significant influence on the assessment and conclusions of EFSA's opinions
- For improving consistency of assessments done by EFSA panels

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4080/epdf

PRIORITIES FOR ONGOING SC WORK PROGRAMME

- Revisited topic list published in 2016

- Possible future activities as resources freed up
  - Non-monotonic dose response
  - Benchmark dose modelling for human data
  - Predictive microbiology dose-response modelling
  - Interpretation of epidemiological studies
  - Guidance on harmonisation of criteria for history of use

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4502/full

SCIENTIFIC CRITERIA FOR UPDATING?

- New data
  - ✓ Relevance and reliability?
  - ✓ Previously identified data gaps?
  - ✓ Likely to affect significantly previous assessment?
- New assessment methodology
  - ✓ Critical new data requirements?
  - ✓ New approaches for hazard and exposure assessment?
  - ✓ Implications of new guidance?
  - ✓ Exposure close to HBGV or Margin of Exposure

Any decision to update requires careful consideration by EFSA management, risk managers and stakeholders

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4737/full

THANKS

UNCERTAINTY IS AN UNCOMFORTABLE POSITION. BUT CERTAINTY IS AN ABSURD ONE

VOLTAIRE

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