



Workshop on Increasing Robustness, Transparency and Openness of Scientific Assessments

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EVIDENCE-BASED SCIENTIFIC ASSESSMENT

Robust, transparent and open

- Rigorous assessment methodologies to collect, evaluate and integrate evidence
- Systematic description of data used
 - Data selection (sources and literature)
 - Data validation
- Assumptions
- Uncertainties
- Integration of different lines and strengths of evidence
- Unambiguous and transparent communication
- Fit for purpose



THE BIG PICTURE

Evidence-based scientific assessment demands scientific robustness using rigorous methodologies, together with transparent and open communication of processes and results.

- Overall framework for evidence-based scientific assessment
- Guidance on analysis of uncertainty
- Guidance on weight of evidence
- Guidance on biological relevance
- Guidance on opinion structure and content
- Guidance on guidance lifecycle

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EDITORIAL



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Increasing robustness, transparency and openness of scientific assessments

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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 and results of the assessment. A structured and clearly documented approach is essential if the outcome of the scientific assessment is to be communicated unambiguously to decision makers, the wider scientific community and stakeholders. This will help to clearly focus on key issues and allow reproducibility of the assessments between expert groups and organisations.

WORKSHOP OBJECTIVES

To collect relevant information and to engage with EFSA partners to facilitate harmonisation, acceptance and implementation of the methodological approaches developed by EFSA

- To present TORs of the working groups on weight of evidence and biological relevance, to clarify objectives and scope of resulting guidance documents, capture ideas and relevant work
- To collect comments from EFSA partners on the draft guidance on uncertainty in scientific assessments
- To present and collect comments on the first deliverable of the EFSA Prometheus project (Scientific Report on “Principles and process for dealing with data and evidence”)

OVERALL FRAMEWORK PROMETHEUS PROJECT

PROMoting METHods for Evidence Use in Scientific assessments

- Set principles and processes for evidence use in scientific assessments and analyse the methods currently applied by EFSA
- Support harmonisation and coordination of other EFSA projects to develop tools
- EFSA Assessment and Methodological Support (AMU) Unit in consultation with SC
- **Outputs**
 - Methodological framework report (2015)
 - Analysis of methodologies applied by EFSA for evidence use in scientific assessments (2016)



ARE YOU SURE?

Analysis of Uncertainty in Scientific Assessments

- Guidance for identification, characterisation and communication of uncertainties
- Qualitative, semi-quantitative and quantitative methods (toolbox)
- WG of the Scientific Committee
- Draft Guidance 2015 now published for public consultation, review comments
- 1 year testing by Panels
- Review experience, final adoption early 2017

COMBINED LINES OF EVIDENCE

Weight of Evidence

- Guidance to combine different strands of evidence in consistent and transparent way
- From experimental studies in humans, animal or cell-based assays, computational models, surveillance or new emerging tools
- WG of the Scientific Committee
- Public consultation on draft guidance
- Guidance adopted in 2017



ADVERSE EFFECTS

Biological Relevance

- Guidance will focus on scientific criteria to distinguish observed adverse or positive health effects from homeostatic or adaptive responses for the considered target species
- WG of the Scientific Committee
- Public consultation on draft guidance
- Guidance adopted in 2017



WIDER CONTEXT

Collaboration and Consultation

- EFSA's sister Agencies, EC non-food Committees, Member States, international bodies
- Public consultation prior to each final adoption
- European and wider international workshop planned after completion (2017)
- "Open EFSA" to achieve in next 5 years
 - improving overall quality of information and data used for outputs
 - complying with normative and societal expectation

GRAZIE MILLE

ANY QUESTIONS?

