



UPDATE FROM THE SCIENTIFIC COMMITTEE

**Management Board meeting
14 December 2016**

81ST SC PLENARY 16-17 NOVEMBER 2017

Open Plenary with 20+ observers

- Draft Guidance Documents
 - Weight of Evidence
 - Biological Relevance
 - Benchmark Dose Approach
- Scientific criteria to consider updating an EFSA scientific assessment

WEIGHT OF EVIDENCE GUIDANCE DOCUMENT

SCOPE

The guidance document aims to:

- ✓ provide, in answering a scientific assessment question, a general framework for considering and documenting the approaches used to weigh the evidence;
- ✓ indicate, in general terms, types of qualitative and quantitative approaches to weigh and integrate evidence;
- ✓ list individual methodologies with pointers as to where details of these can be found; and
- ✓ provide suggestions for conducting and reporting of weight of evidence and evidence integration

Weight of evidence assessment

1. Assemble the evidence
2. Weigh the evidence
3. Integrate the evidence


may occur at one or more points in the assessment, where evidence integration is needed

BIOLOGICAL RELEVANCE GUIDANCE DOCUMENT

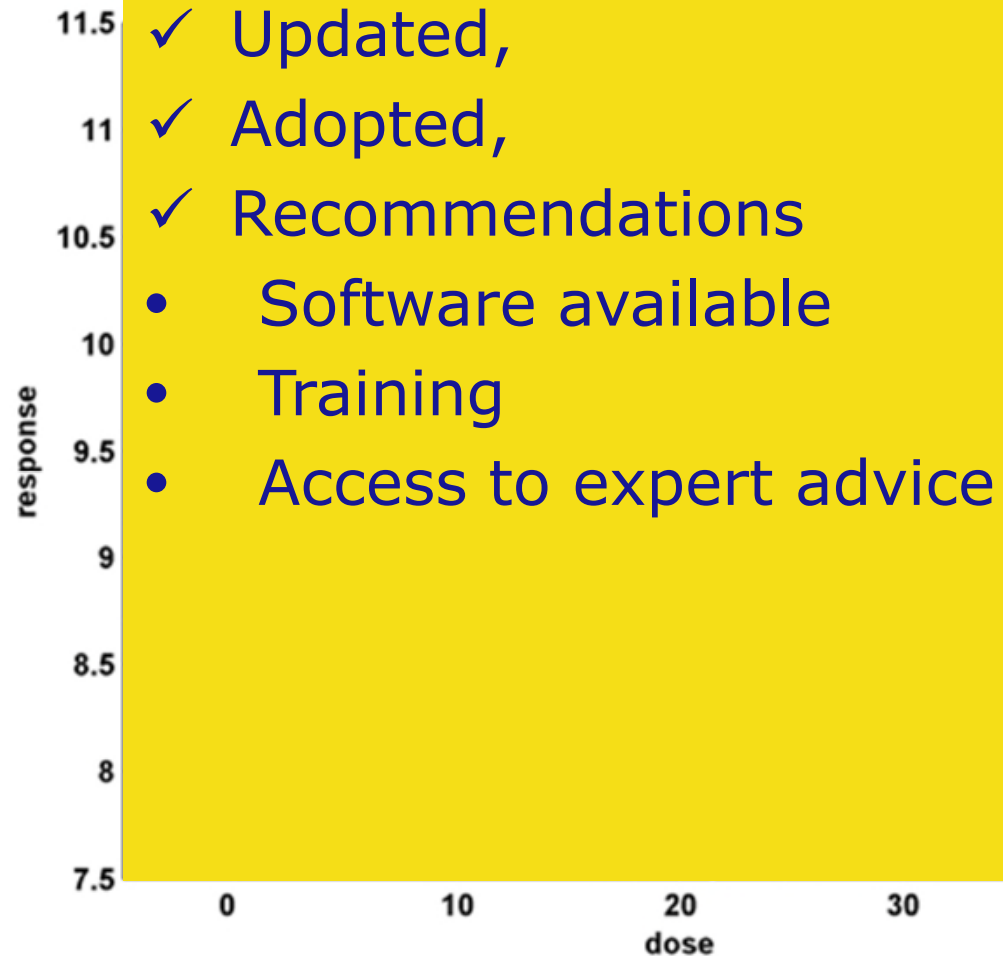
Terms of Reference

- ❖ Definitions and concepts (adverse, adaptive, harm, homeostasis, biological threshold etc.)
- ❖ List of criteria (e.g. nature and size of the biological changes)
- ❖ Case studies
- ❖ Links with on-going EFSA activities


BENCHMARK DOSE APPROACH GUIDANCE

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- A vertical collage on the left side of the slide showing various food items and a landscape. From top to bottom: a black and white cow, a pile of brown eggs, a green landscape with a river, a bunch of purple grapes, and a pile of red strawberries. Below the strawberries are several white stars of varying sizes.
- 2009 SC adopted guidance on the use of BMD approach instead of the No-Observed-Adverse-Effect-Level (NOAEL) approach to derive a reference point (departure point) from the critical dose-response data to establish health-based guidance values and margins of exposure.
 - 2014 SC agreed to review experience and update statistical guidance.

THE BMD APPROACH



SCIENTIFIC CRITERIA FOR UPDATING?

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- **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