




Report from the Scientific Committee

ROLE OF THE SCIENTIFIC COMMITTEE

To provide scientific advice

- 
- on new and harmonised approaches for scientific assessments in EFSA's sectors
 - on multi-sectoral issues
 - and strategic advice to EFSA's Executive Director
 - and to ensure consistency of guidance development.

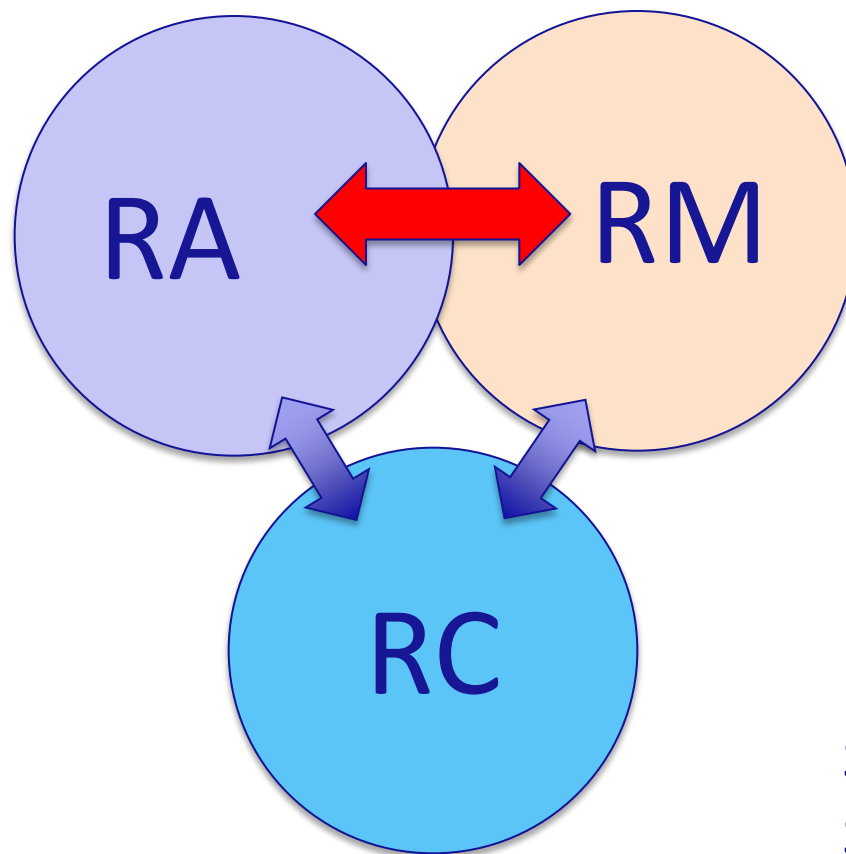
16 independent scientific experts (10 chairs of Panels plus 6 non-Panel), Working Groups

EVIDENCE-BASED SCIENTIFIC ASSESSMENT

Robust, transparent and open

- Systematic description of data used
 - Data selection (sources and literature)
 - Data validation
- Rigorous assessment methodologies
- Assumptions
- Uncertainties
- Integration of different lines and strengths of evidence
- Fit for purpose

RISK ANALYSIS PARADIGM



Decision makers
Stakeholders
Scientific Community

[FAO/WHO 1997]

ROADMAP AND WHERE WE ARE GOING

RA Opinions

Guidance Documents

Preparatory work

Priorities
 For Guidance
 Development
 2013

**Endocrine
 disruptors**
 Characterisation
 criteria and test
 methods
 2013

**Qualified Presumption
 of Safety approach**
 Safety assessment of
 botanicals
 2014

Carvone
 Safety assessment
 2014

**Emerging Risks
 Standing WG**

**Guidance Review
 Standing WG**

**Robust,
 transparent, open
 scientific
 assessment**



EXAMPLES OF OPINIONS

RA opinions

Carvone

Endocrine Disruptors

Insects as food and feed

Methodology

Environmental risk assessment

Benchmark Dose

Guidance

Botanicals Qualified Presumption of Safety

Uncertainty

Weight of Evidence

Biological Relevance

Standing Working Groups

Emerging Risks

Guidance Review – opinion content, life-cycle



PREPARATORY WORK

- **Non-monotonic dose response**
Colloquium 2013, procurement
- **Mixtures**
Cumulative RA (pesticides), Colloquium 2014
- **Bees**
Task Force, Colloquium 2013, EFSA reports and procurements
- **Risk Ranking**
procurement
- **New toxicology methods (molecular, omics)**
ongoing reviews

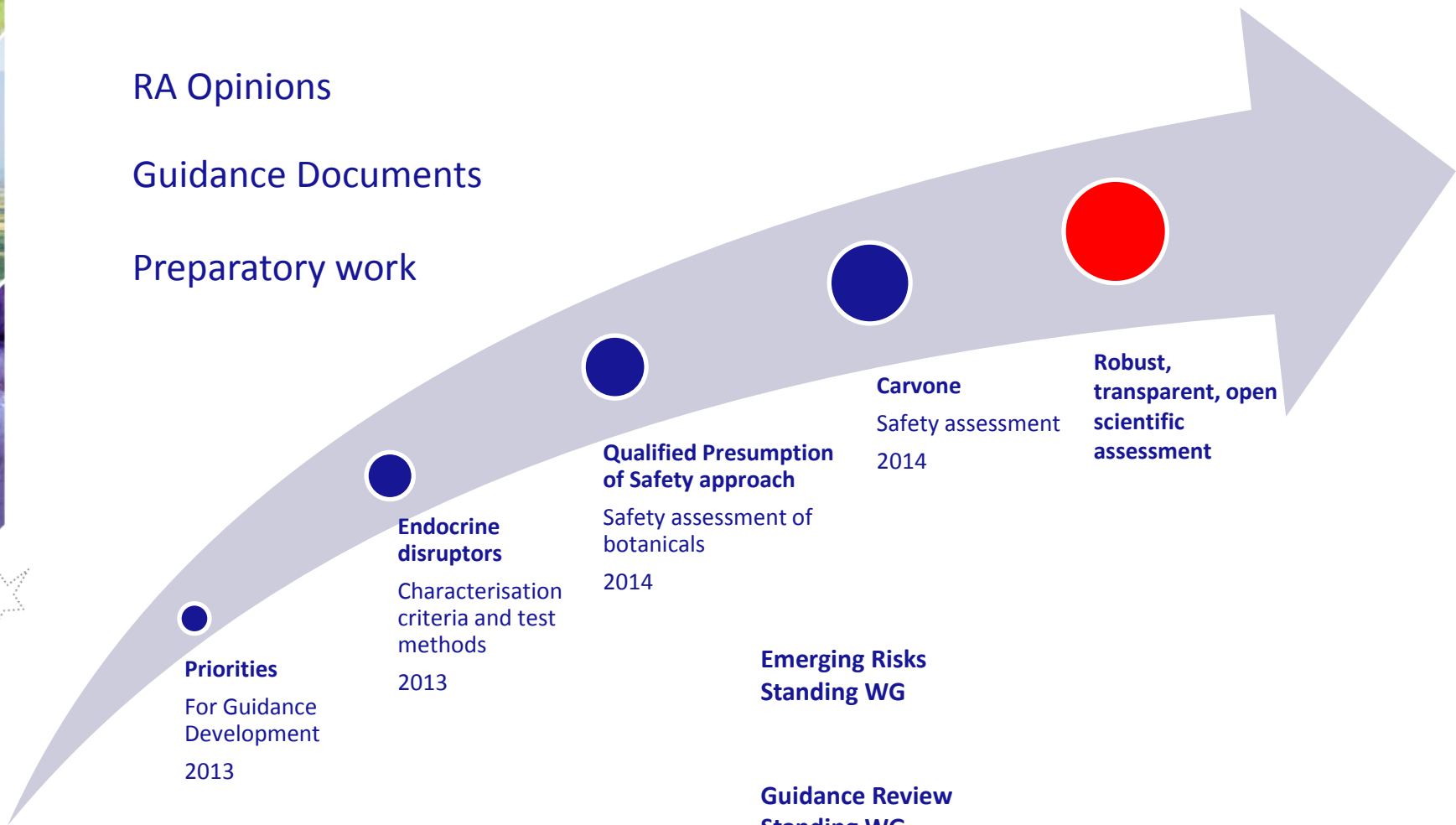
TOWARDS THE BIG PICTURE



RA Opinions

Guidance Documents

Preparatory work





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

OVERALL FRAMEWORK

Promoting Methods for Evidence Use in Science (Prometheus Project)

- set principles of EFSA scientific assessments and review available methods
- support harmonisation and coordination of other EFSA projects to develop tools
- led by EFSA Assessment and Methodological Support (AMU) Unit
- Outputs
 - Methodological framework report (2015)
 - Gap and impact analysis of methods (2016)
 - Analysis of regulated product fields (regulatory frameworks and guidance)(2016)

A vertical collage on the left side of the slide featuring a black and white cow, a pile of brown eggs, a landscape with a winding river, a bunch of purple grapes, and a basket of strawberries. Below the collage are several white dotted stars of varying sizes.

ARE YOU SURE?

Analysis of Uncertainty

- Guidance for identification, characterisation, documentation
- Qualitative, semi-quantitative and quantitative methods
- WG of the Scientific Committee
- Guidance 2015
- 1 year testing by Panels

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
- Guidance end 2016



ADVERSE EFFECTS

Biological Relevance

- Guidance to distinguish observed adverse or positive health effects from homeostatic or adaptive responses
 - WG of the Scientific Committee
 - Guidance end 2016
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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 (consultation to 15 Oct)