



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



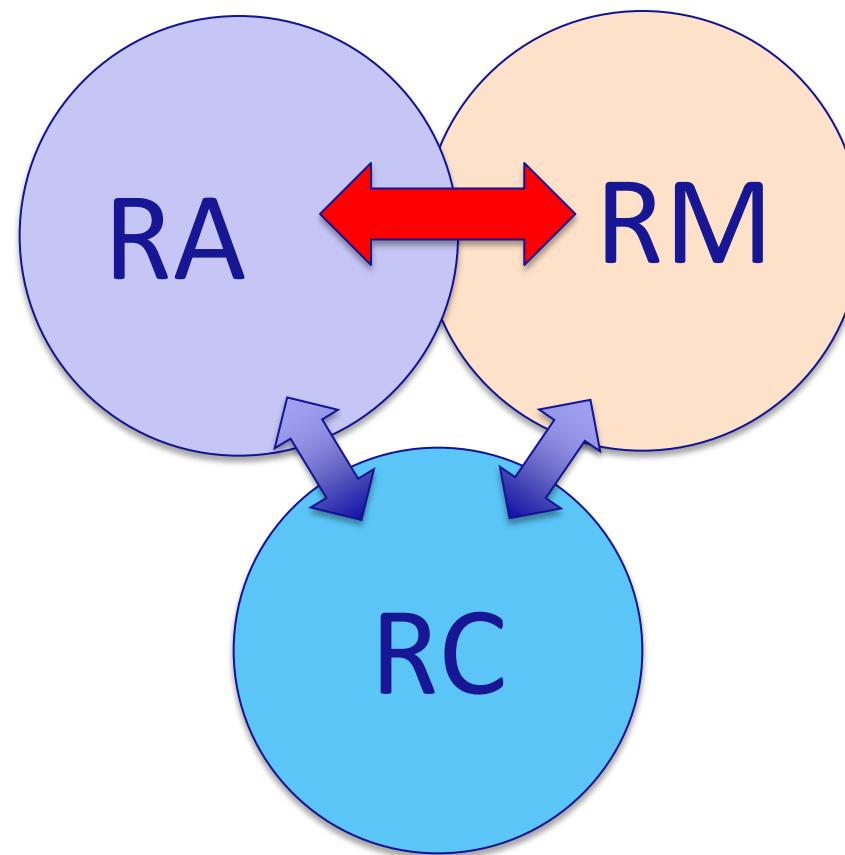
EVIDENCE-BASED SCIENTIFIC ASSESSMENT

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

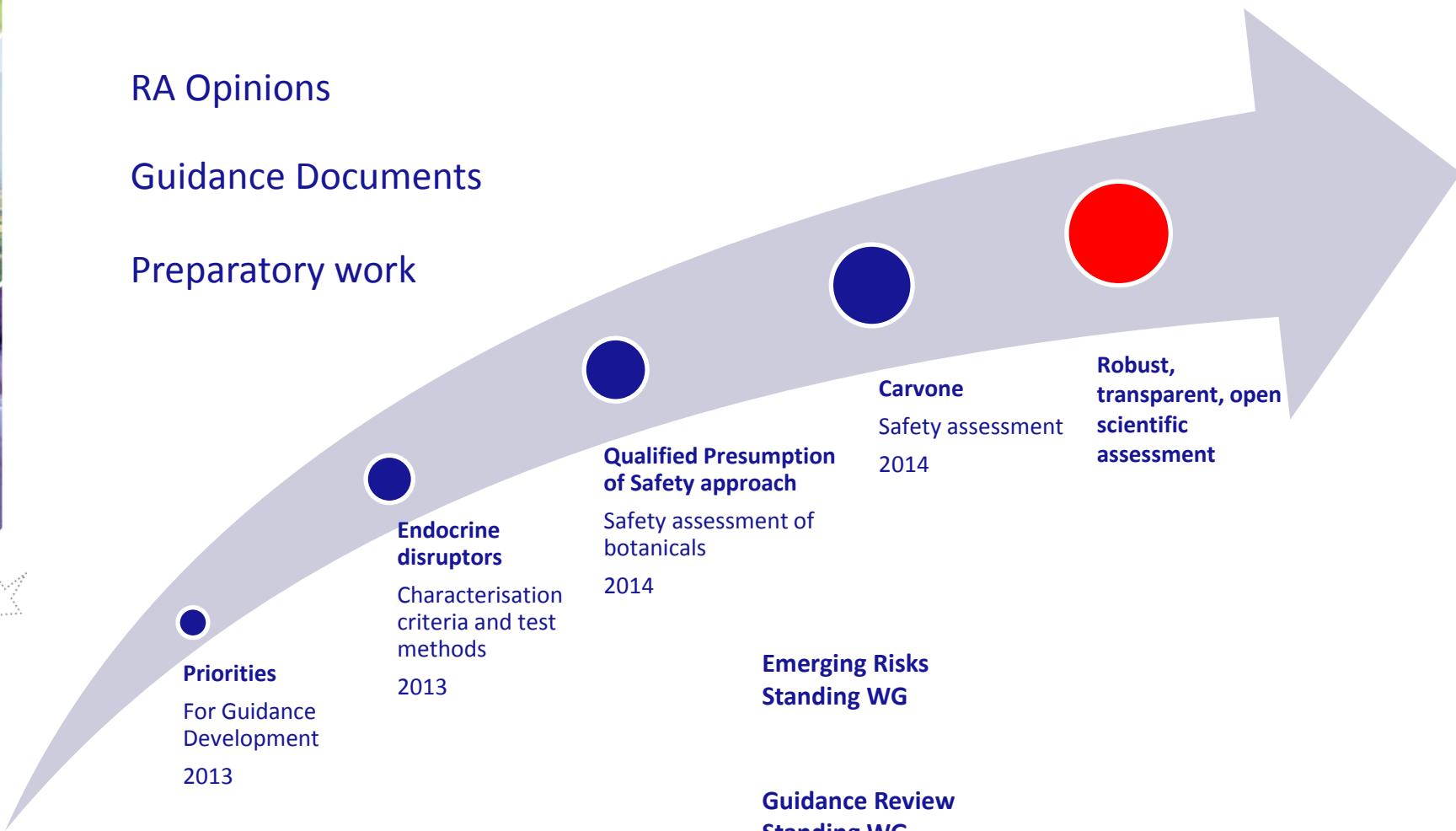
**Qualified Presumption
of Safety approach**
Safety assessment of
botanicals
2014

**Emerging Risks
Standing WG**

**Guidance Review
Standing WG**

Carvone
Safety assessment
2014

**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

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Qualified Presumption
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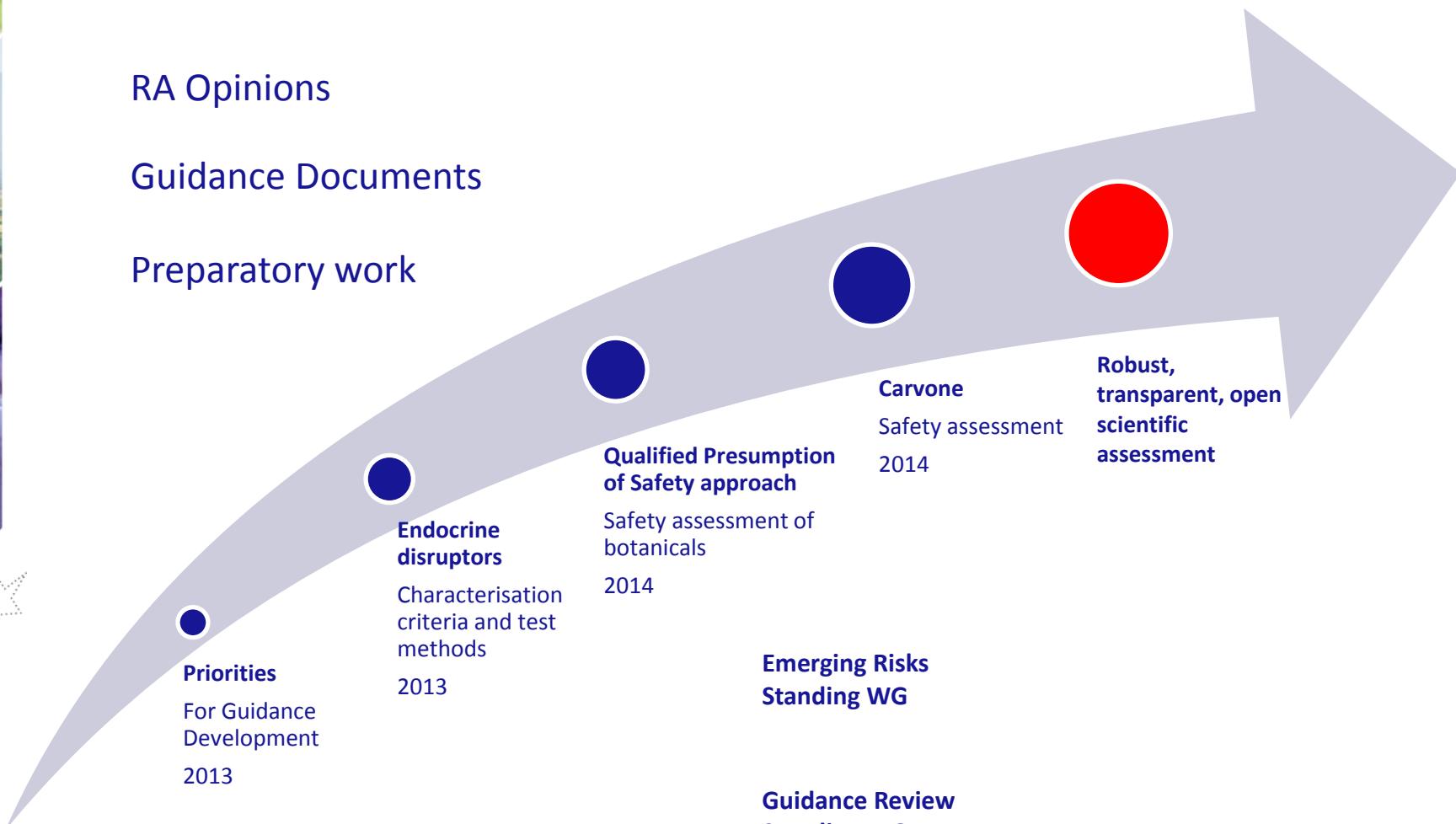
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Robust,
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THE BIG PICTURE

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 decorative collage on the left side of the slide, featuring images of a cow, eggs, a landscape, and strawberries, with a dotted star pattern running along the bottom.

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



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)