



Principles and process for dealing with data and evidence

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SCIENTIFIC REPORT



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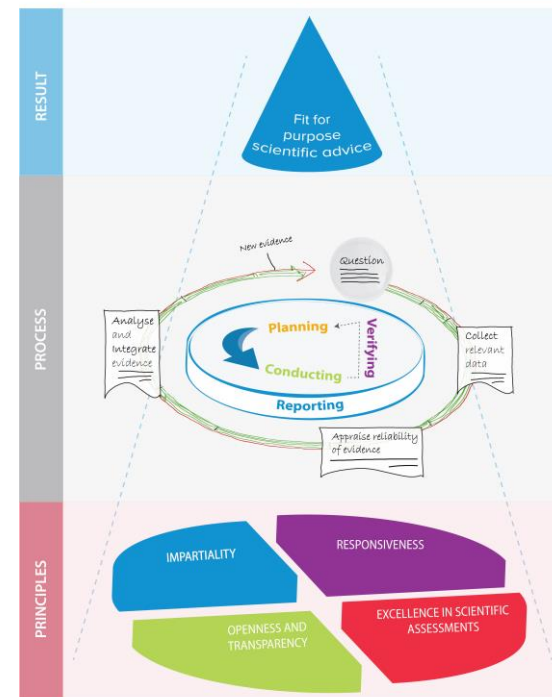
Principles and process for dealing with data and evidence in scientific assessments

European Food Safety Authority (EFSA)

EFSA Journal 2015;13(5):4121[36 pp.]. doi:10.2903/j.efsa.2015.4121

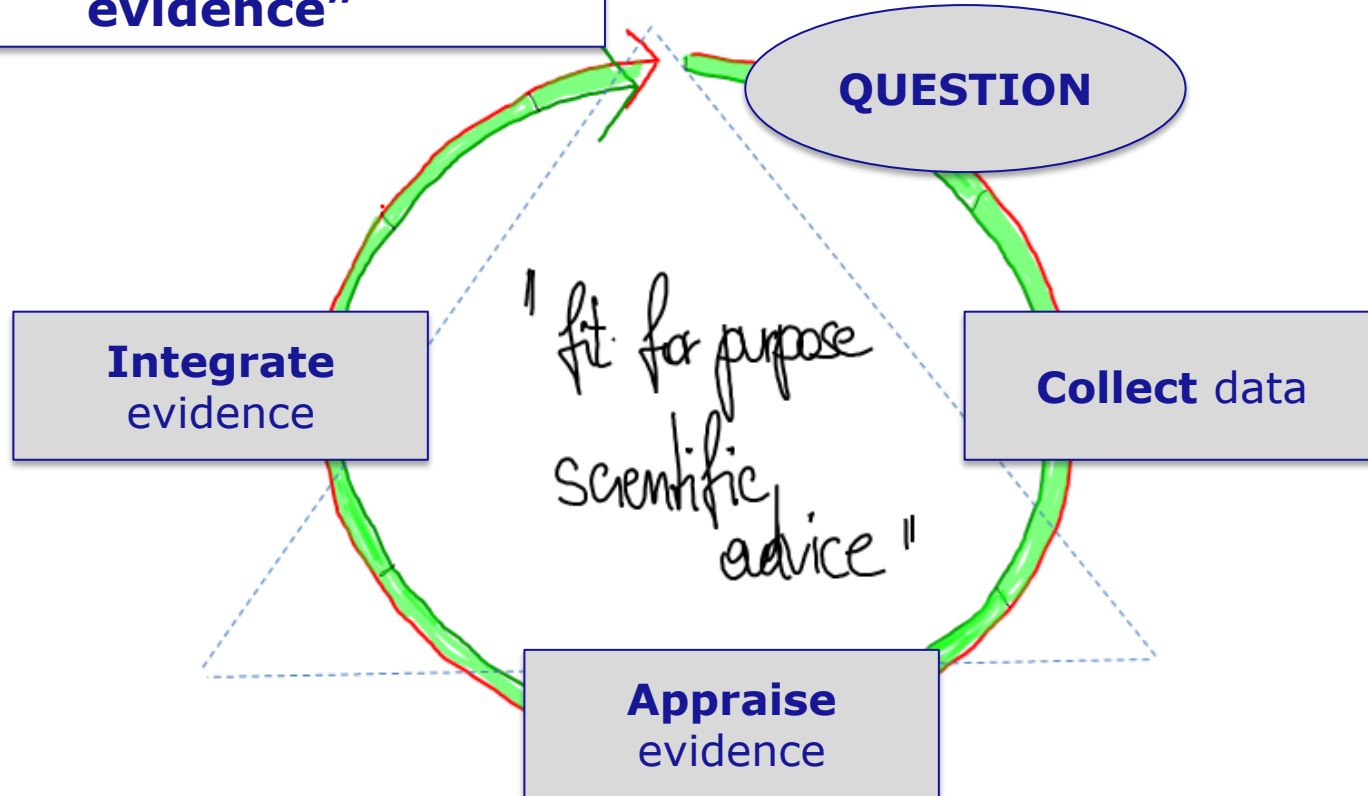
- ❑ DLV 1 of EFSA PROMETHEUS project
- ❑ Prepared by a task force of EFSA staff
- ❑ Endorsed by EFSA SC

Promoting Methods for Evidence Use in Scientific assessments



You can read the full report at <http://www.efsa.europa.eu/en/publications/efsa-journal.htm>

"Dealing with data and evidence"



"Dealing with
data and
evidence"

QUESTION

Integrate
evidence

Collect data

Appraise
evidence

*"fit for purpose
scientific
advice"*

RELEVANCE

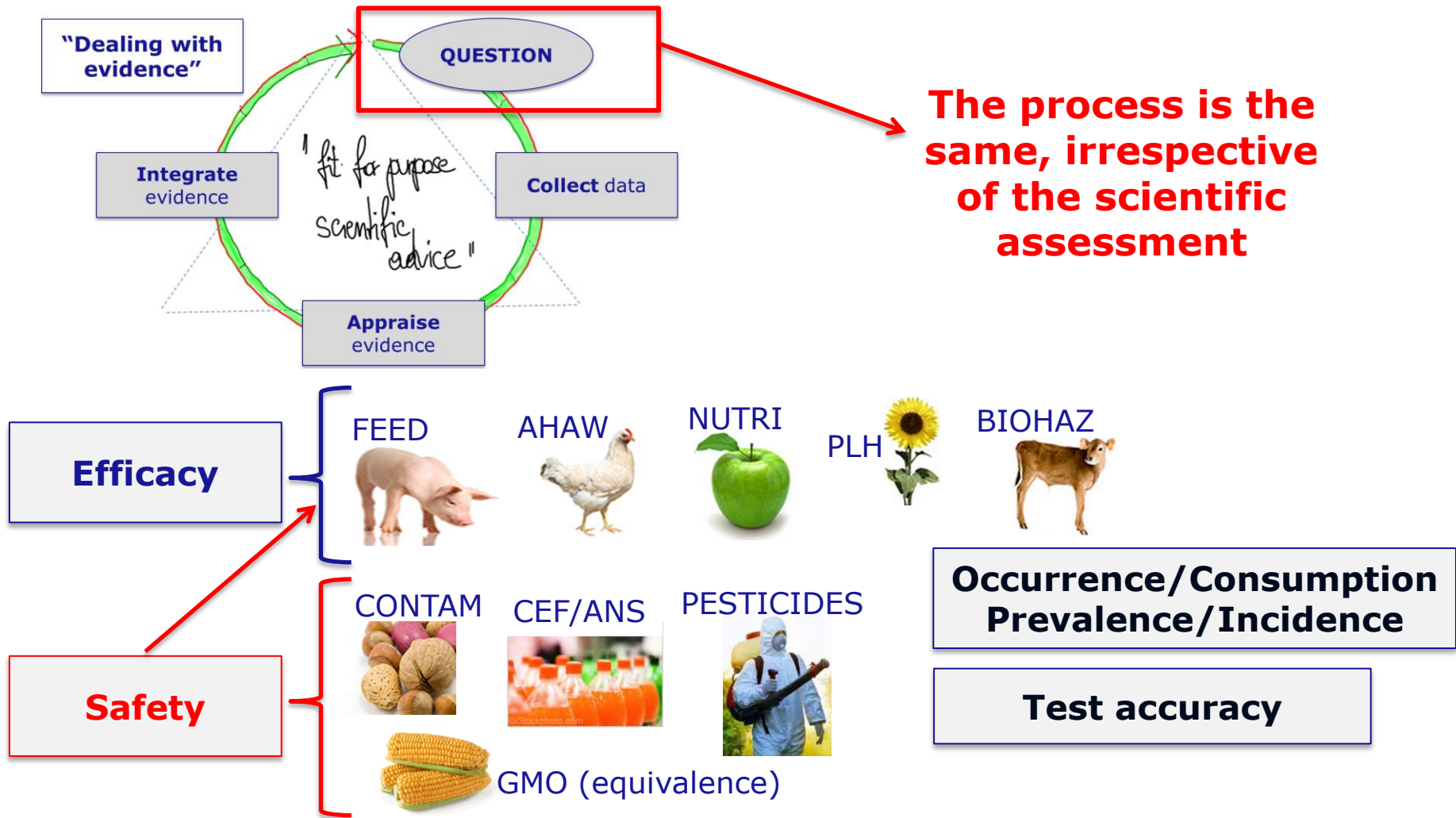
Extent to which the available
data address the objectives of
the assessment

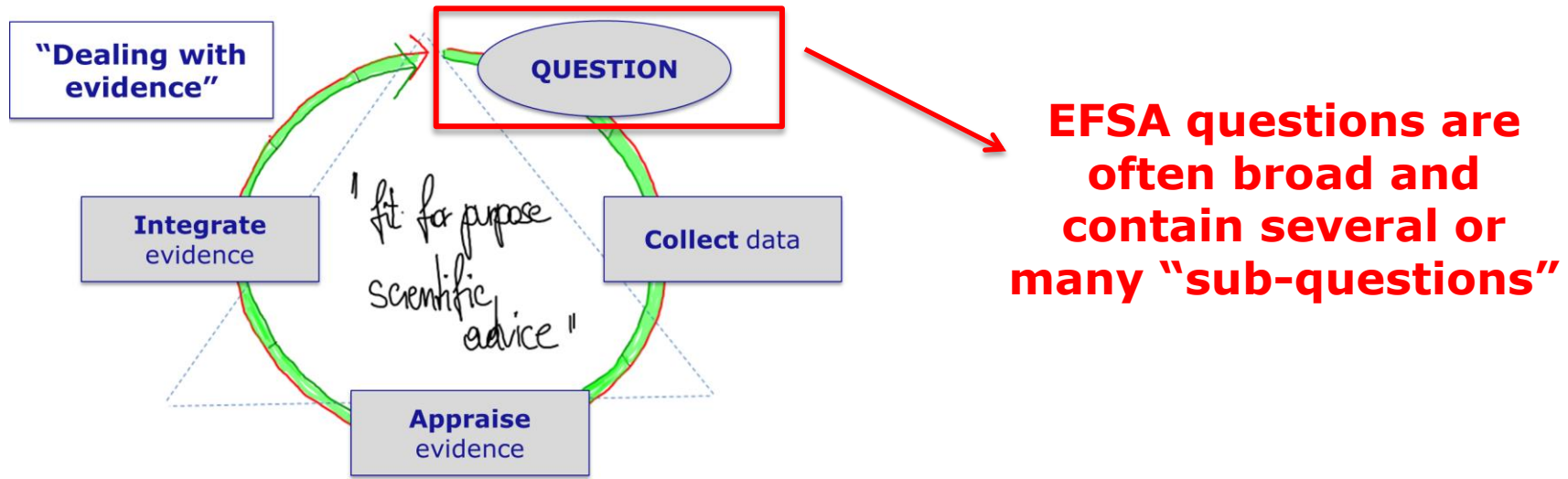
**WEIGHT OF
EVIDENCE**

- ☐ Relevance
- ☐ Reliability

RELIABILITY

- ☐ Accuracy (systematic error)
- ☐ Precision (random error)





A sub-question is a scientific question that can be answered by an experiment or observational study (or as a single question in an expert elicitation study) without being further broken down

EXAMPLES OF EFSA SUB-QUESTIONS

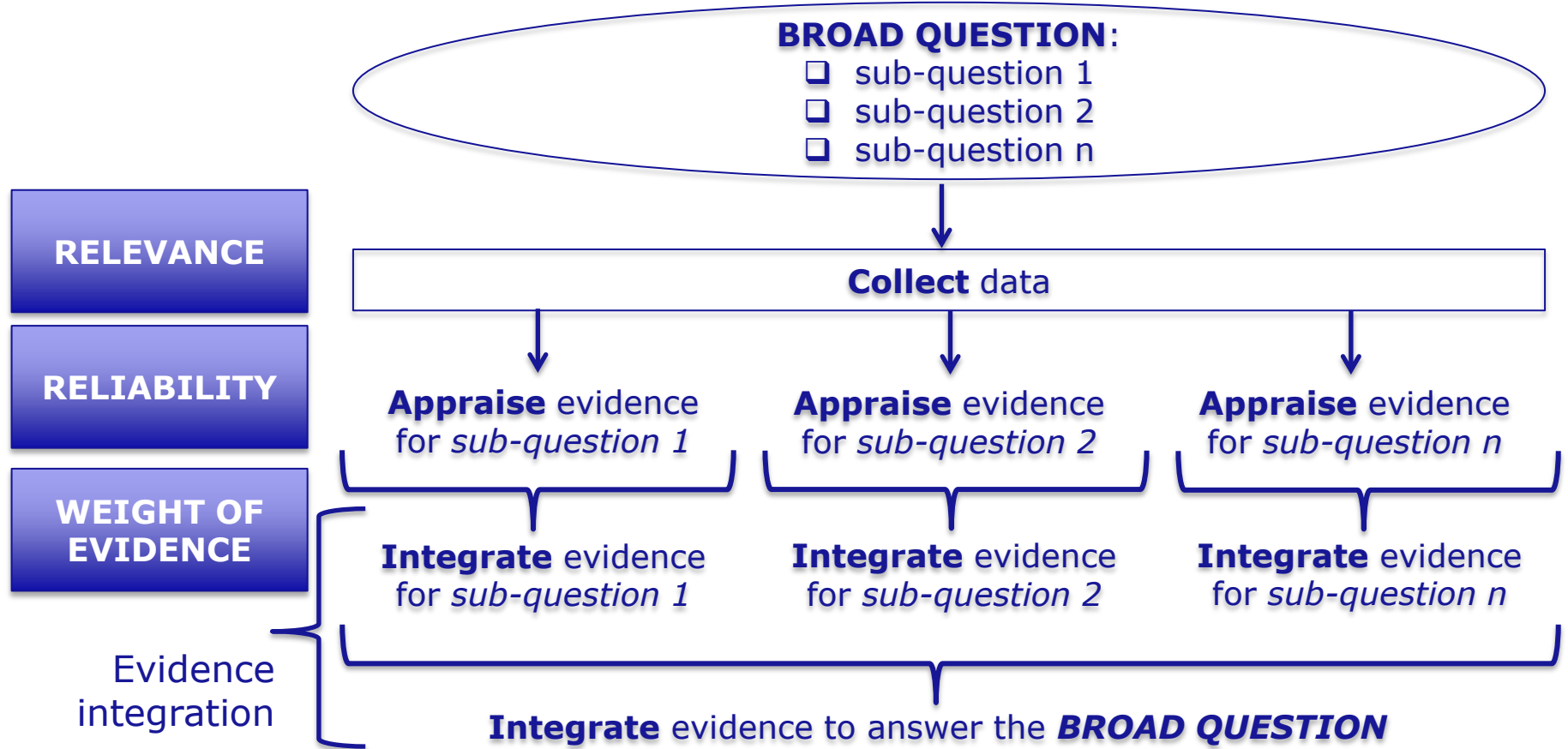
CHEMICAL RA

- Association exposure-outcome in humans
 - Association exposure-outcome in animals
 - Association exposure-outcome in vitro
 - etc
- for H IDENTIFICATION

- Occurrence
 - Consumption
 - etc
- for EXPOSURE ASSESSMENT

IMPORT Risk Analysis

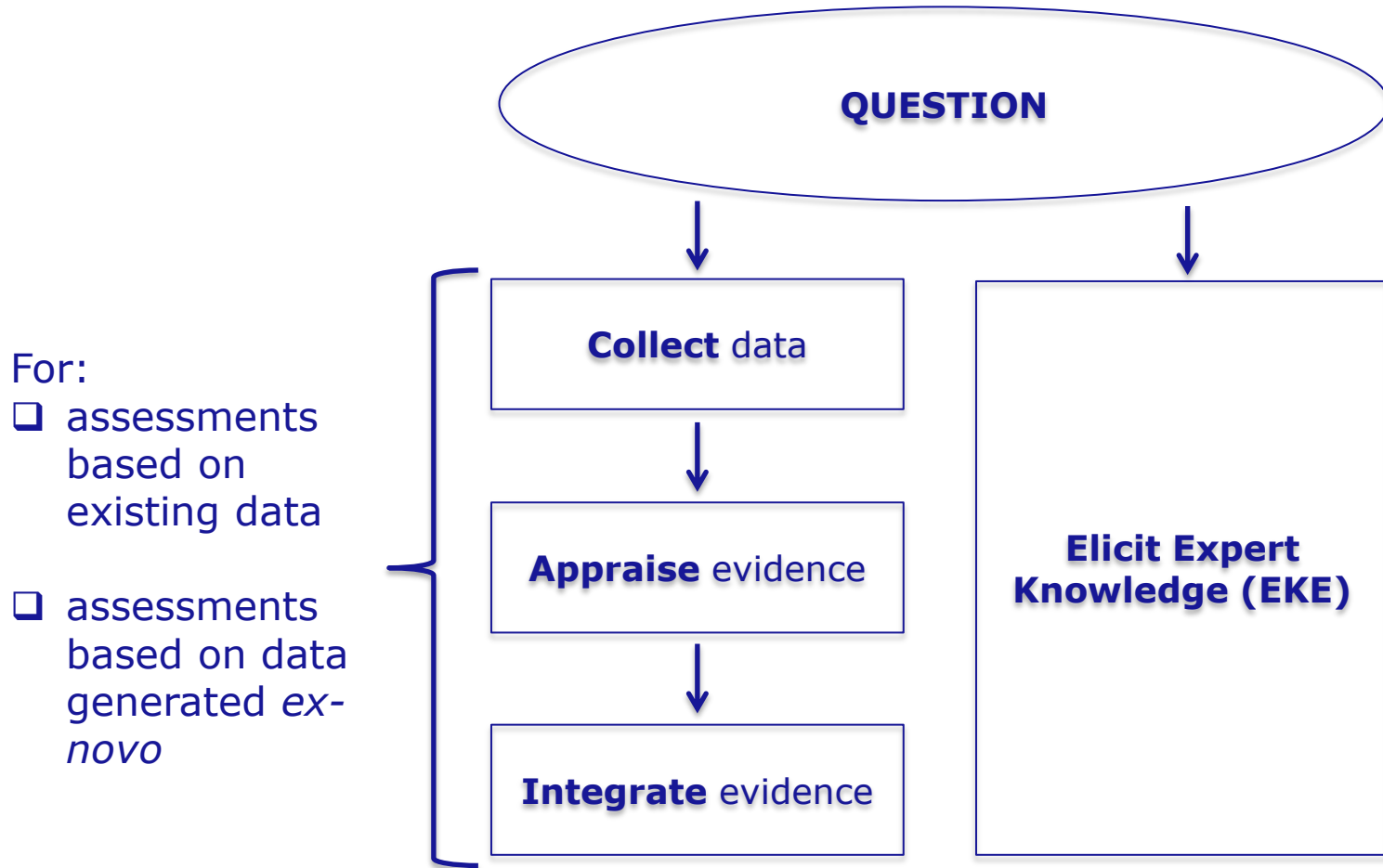
- Prevalence in country of origin
 - Diagnostic test accuracy in point of entrance
 - Efficacy of control measures
 - etc
- for RELEASE ASSESSMENT



USE OF EXPERT JUDGMENT

- ❑ To make all decisions in each step of the “collect/appraise/integrate” process
- ❑ As input to the assessment, when data are not available/accessible





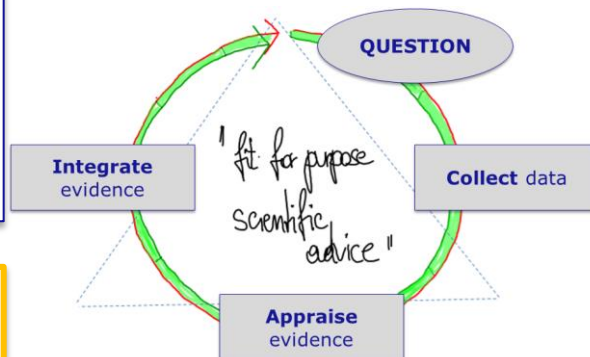
PRINCIPLES FOR DEALING WITH EVIDENCE

Impartiality

Extent to which the assessment is free from preconceptions due to pre-knowledge of results

Openness and Transparency

- ☐ Engaging with relevant parties
- ☐ Clarity and reproducibility



Excellence (Methodological quality)

Use of sound methodological approaches to produce *reliable* results

Responsiveness

Extent to which the assessment answers the original question in a timely manner

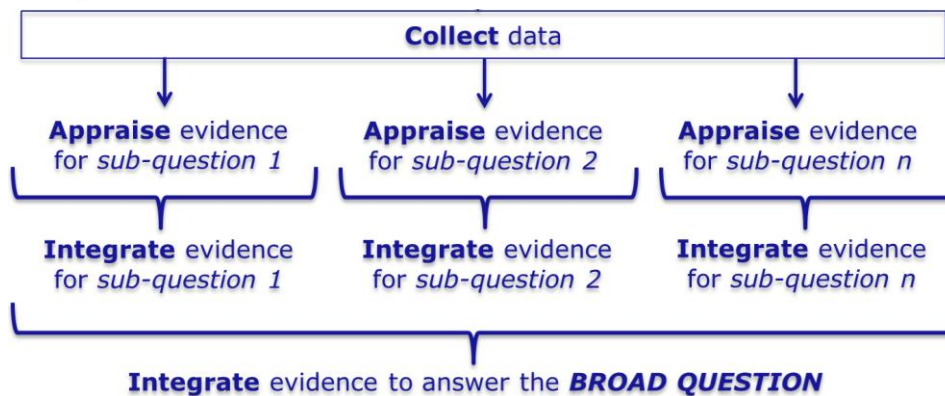
HOW TO FOSTER IMPARTIALITY

**V
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1. PLAN (STRATEGY)

- ☐ Scope
- ☐ Sub-questions
- ☐ Evidence needs
- ☐ What data to collect and how; approach for appraising and integrating data

2. CONDUCT



ITERATIVE PROCESS

- ☐ Expert knowledge
- ☐ Literature scoping
- ☐ Dialogue with requestors

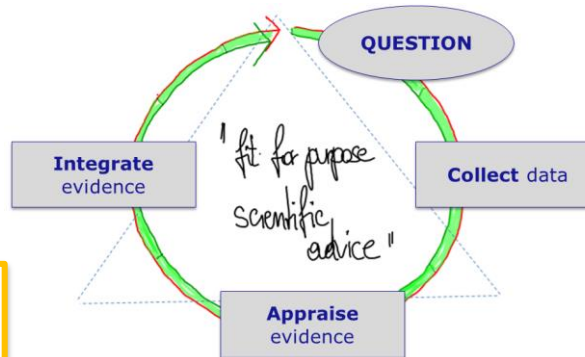
QUESTIONS for breakout groups:

- ☐ Is the strategy definable upfront?
- ☐ If not, what are the risks?

PRINCIPLES FOR DEALING WITH EVIDENCE

Impartiality

**Excellence
(Methodological
quality)**



**Openness and
Transparency**

Responsiveness

- ☐ Engaging with relevant parties
- ☐ Clarity and reproducibility

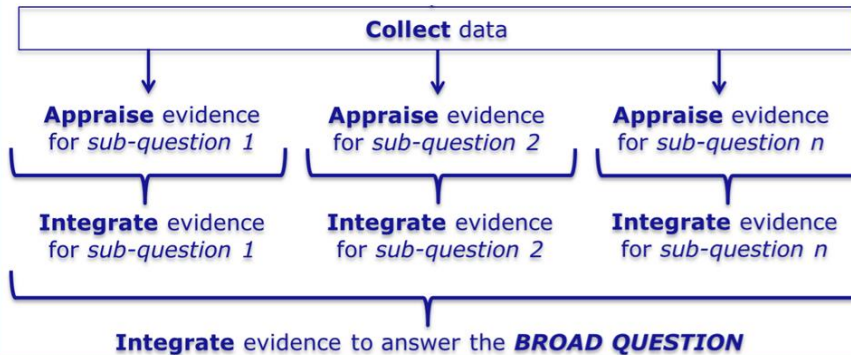
HOW TO FOSTER TRANSPARENCY AND OPENNESS

**V
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PLAN (STRATEGY)

- ☐ Scope
- ☐ Sub-questions
- ☐ Evidence needs
- ☐ What data to collect and how; approach for appraising and integrating

CONDUCT



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- ☐ Methods and results
- ☐ Make data available
- ☐ Share the strategy for the assessment before initiating it

PRINCIPLES FOR DEALING WITH EVIDENCE

Impartiality

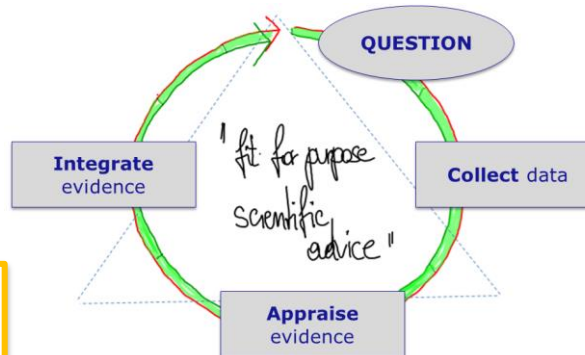
Excellence (Methodological quality)

Use of sound methodological approaches to produce *reliable* results

Openness and Transparency

Responsiveness

Extent to which the assessment answers the original question in a timely manner



PLAN (STRATEGY)

- ❑ Scope
- ❑ Sub-questions
- ❑ Evidence needs
- ❑ What data to collect and how; approach for appraising and integrating
 - *Tailor the methodology to deliver an assessment that is fit-for-purpose*

CONDUCT

APPROACH 0 (simplest)	APPROACH 1 (more complex)	APPROACH n (most complex)
e.g. use expertise of the WG	e.g. "rapid review"	e.g. "systematic review"

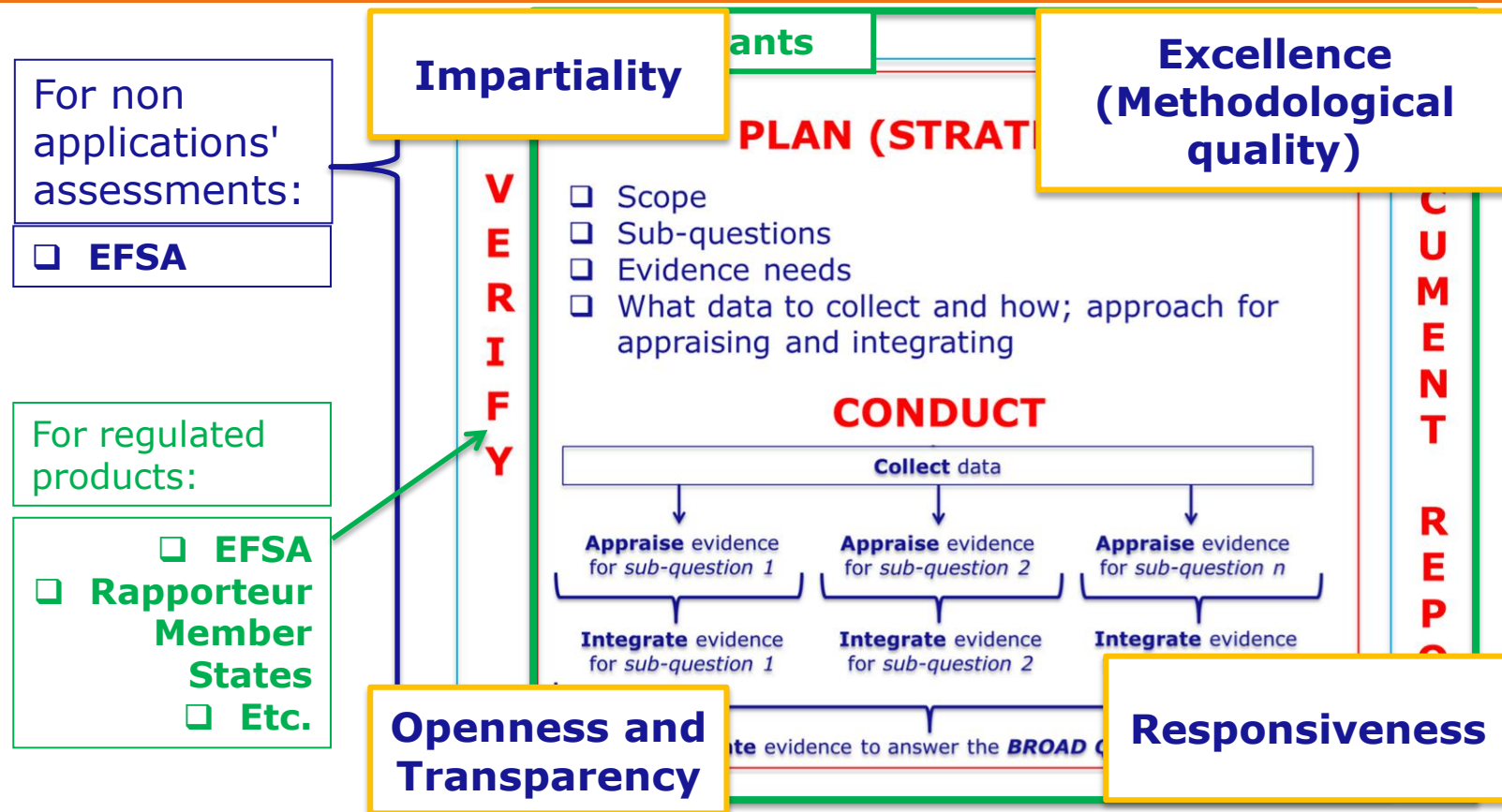
PROMETHEUS APPROACH IN THE EFSA CONTEXT

EFSA conducts 2 types of assessment

- “Non-applications” assessments
- Regulated products



DIFFERENT "ACTORS" IN EFSA ASSESSMENTS



GRAZIE MILLE

ANY QUESTIONS?



Acknowledgements:

- ❑ AMU PROMETHEUS team: Laura Martino, Fulvio Barizzzone, Laura Ciccolallo
- ❑ Andy Hart