Guidance on Biological Relevance

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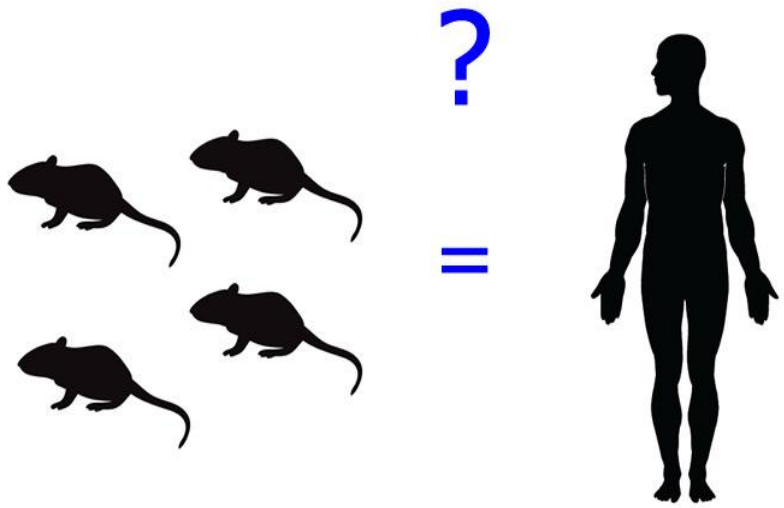
efsa
European Food Safety Authority

BIOLOGICAL RELEVANCE

Objective:

To prepare a Guidance for providing generic issues and criteria to consider biological relevance in relation to evidence used in scientific assessments



Leading Unit and Panel:

Scientific Committee and Emerging Risks Unit – EFSA Scientific Committee

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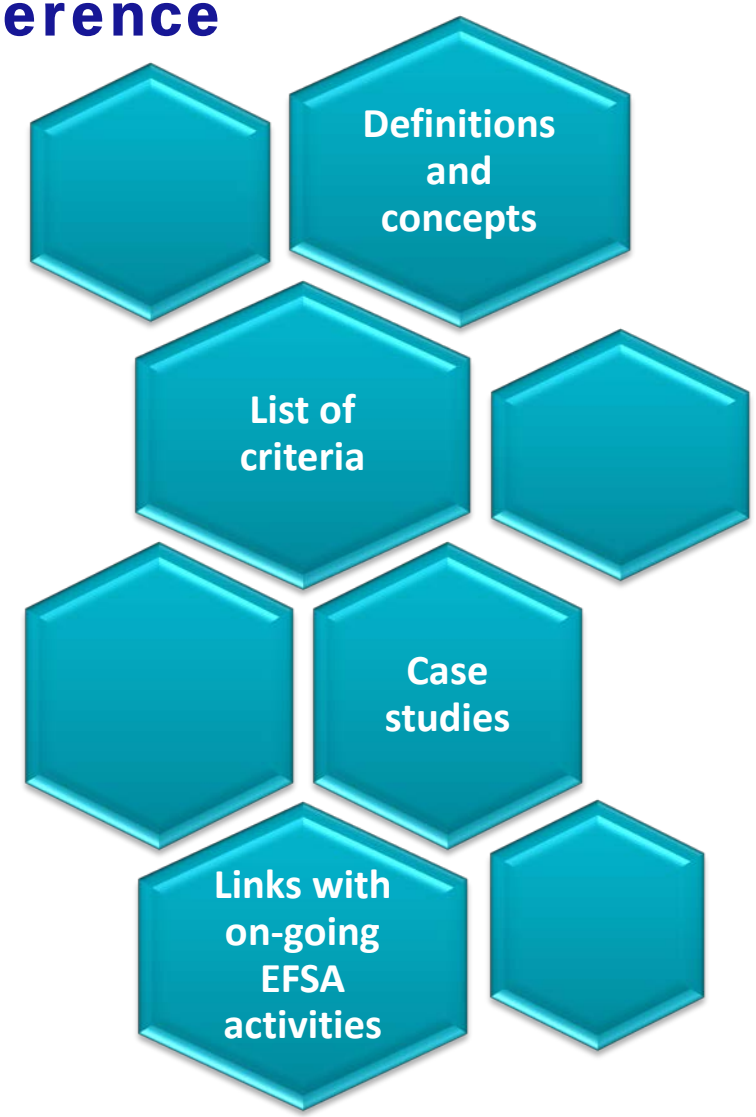
Terms of Reference



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Concepts about biological relevance

Concepts about:

- ✓ Responses of a biological system to exposure
- ✓ What is an Adverse/Beneficial effect?
- ✓ Mode of Action and Adverse Outcome Pathway
- ✓ Thresholds
- ✓ Critical effect
- ✓ Modelling approaches
- ✓ Biomarkers

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Framework for assessing biological relevance

Assessment strategy

Specify the

- Agents
- Subjects
- Effects
- conditions

Collection and extraction of data

Identify evidence / data potentially biologically relevant according to specifications

Appraise and integrate

the relevance of the:

- Agents
- subjects
- effects
- Conditions

in each data set

Uncertainty

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Assessment strategy: Specifications based on question and prior knowledge

The agent(s)

- ✓ E.g. Nutrient, substance, microorganism, pathogen, gene-element or invasive species

The subject

- ✓ What is/are the subjects, populations

The effect

- ✓ Possible effects associated with the exposure to the agents

The conditions

- ✓ What are the relevant conditions regarding the exposure to the agent: duration timing etc.?

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Appraisal of the relevance of the evidence collected

Relevance of the agent

- ✓ Direct evidence on the agent specified
- ✓ Indirect evidence on the agent of interest,
  - ✓ structural analogue, biological agent behaving similar to the biological agent of interest

Relevance of the subject

- ✓ Direct evidence on the subjects specified
- ✓ The use of proxies for subject, test models etc.

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Appraisal of the relevance of the evidence collected

Relevance of the effect (nature and size)

- ✓ Two dimensions of the effect have to be considered:
  - the nature
    - is the effect in itself adverse or beneficial?
    - is the effect directly or indirectly linked to an adverse of beneficial effect?
  - the magnitude
    - for adverse/beneficial effects:
      - is the size outside normal variation?
    - for indirect effects:
      - is the magnitude sufficient for resulting in an adverse/ beneficial outcome?

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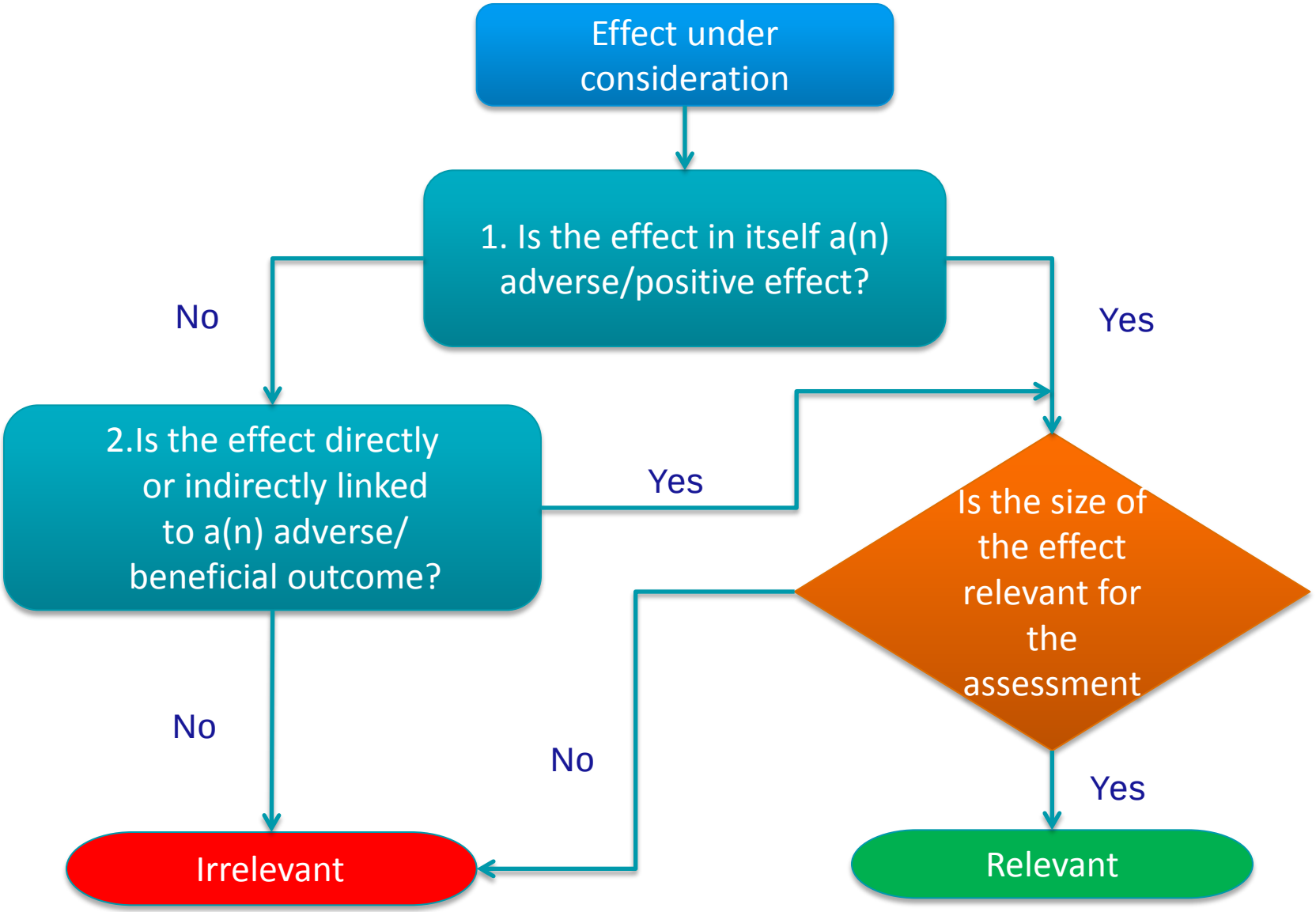

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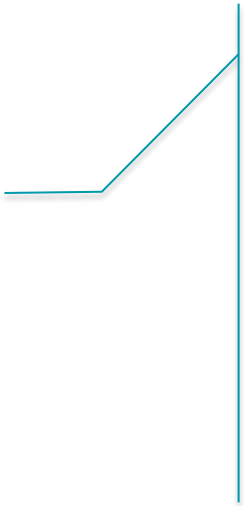
Appraisal of the relevance of the evidence collected

Relevance of the conditions



- ✓ Are the conditions of the study (e.g. epidemiological, environmental, toxicological) used relevant for the assessment questions and as specified in the assesment strategy?

Acknowledgements

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Thank you for your attention

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