



Scientific Guidance and their effect on innovation

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New Guidance documents (technical)

- Assessment of exposure (HH)
- Aneugenicity assessment
- Birds and Mammals
- Soil phototransformation in groundwater
- *Weight of evidence*
- *Uncertainty analysis*
- *Biological relevance of data*
- ...

New Guidance documents (almost ready & upcoming)

- Bees (honey bees + wild bees)
- Statement (PPR Panel) on groundwater monitoring studies
- Impact of water treatment processes on residues of active substances in water abstracted for the production of drinking water (joint EFSA & ECHA)
- Explanatory notes (Micro-organisms)
- Mandate on impact of azole fungicides on the development of azole-resistant *Aspergillus* spp. (joint EFSA, ECHA, EMA, ECDC, EEA, + support of JRC)
- Upcoming:
 - treated seeds (risk assessment) – draft prepared by MS
 - NTA (prioritised)

Prioritisation of drafting/updating GD

- List of GD compiled by MS, EFSA, COM and consulted with stakeholders, including prioritisation
- Process for prioritisation process proposed by MS, EFSA, COM and consulted with stakeholders

Communications complementing data requirements – coming soon

- List of agreed test methods and GD (Part B - microorganisms)
- List of agreed test methods and GD (Part A - chemicals) - Update of the Communications 2013/C 95/01 and 2013/C 95/02
- Planned: additional database with Guidelines and supporting documents

GD and innovation

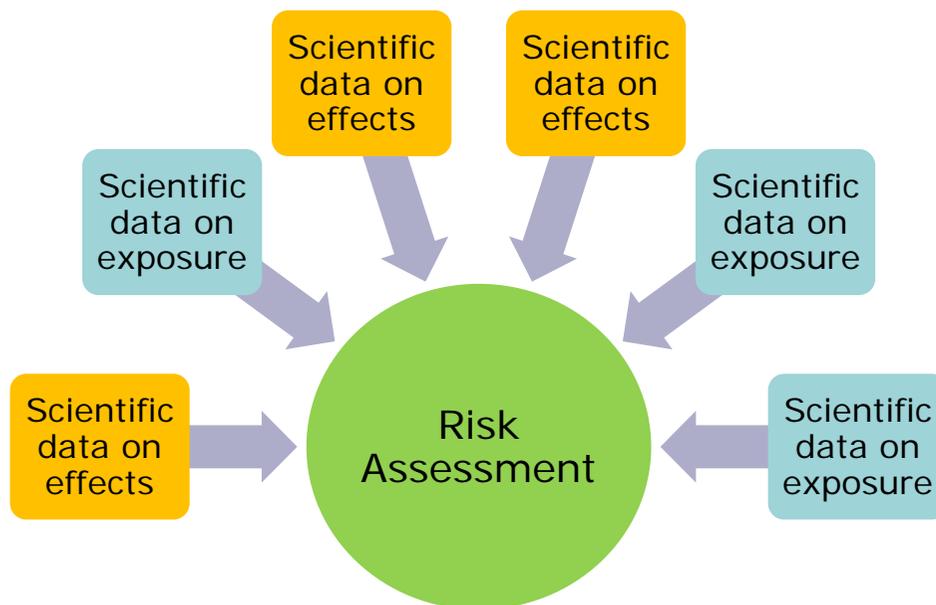
- GD facilitates RA and harmonisation (agreement on methods)



Science keeps evolving

- GD may not cover all cases
 - particular properties of AS & innovative AS
 - Particular way of using AS
 - Higher tier RA
- GD may need updates on science and new evidence/data

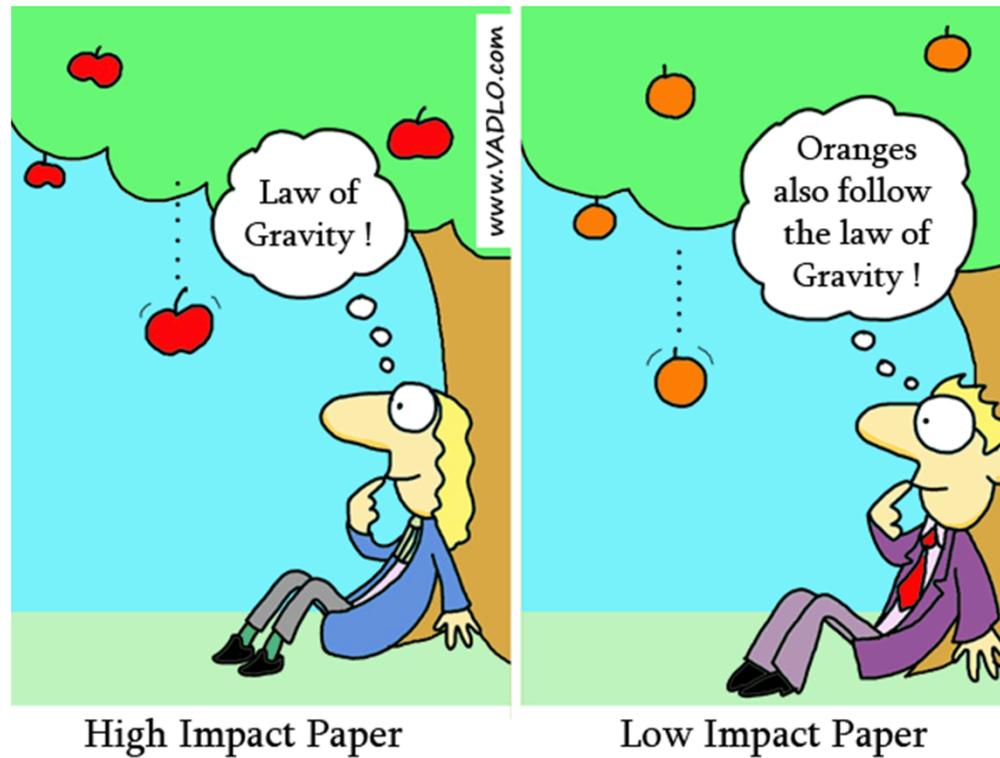
Risk Assessment is based on science



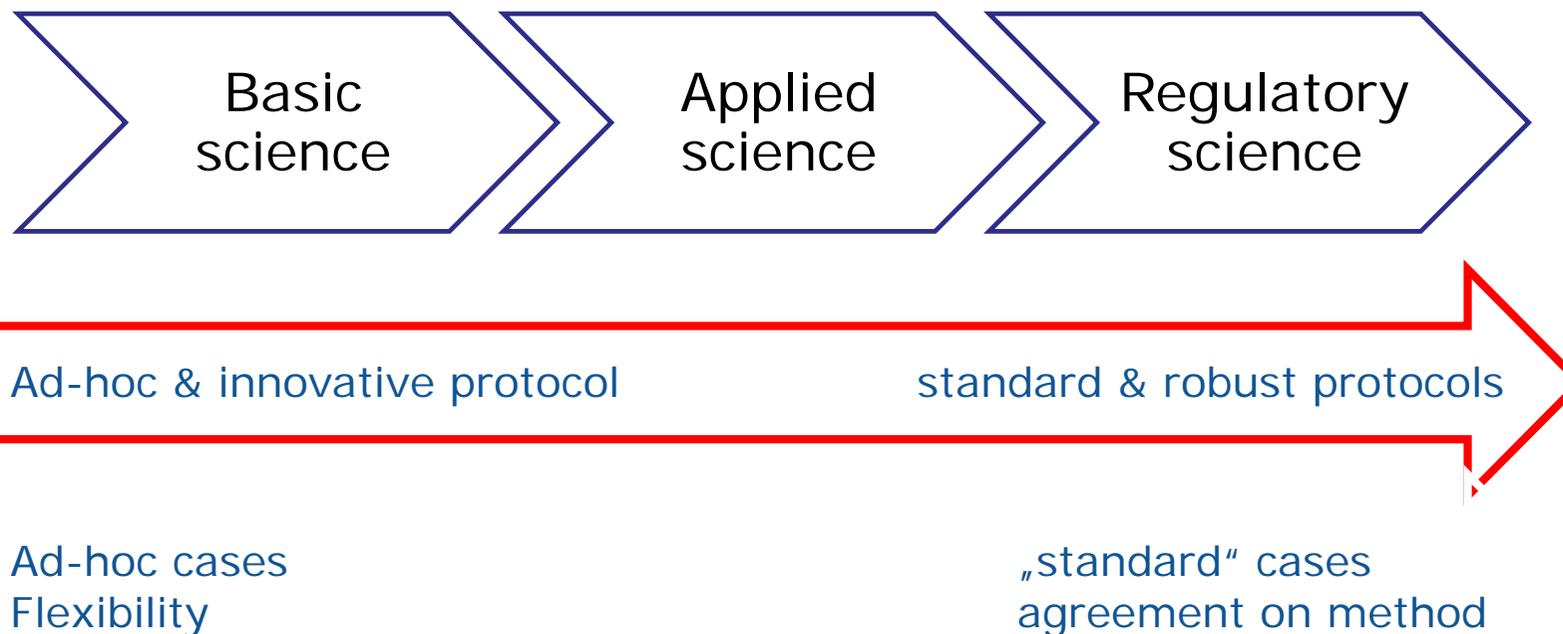
**RA based on scientific guidance documents
helps to harmonise and facilitates peer review (agreement on methods)**



Not all scientific data are the same



Not all Scientific Data are the same



Increasing complexity of risk assessment



"need to know"
information



"nice to know"
information

*Biopesticides and natural substances:
time to access to the market*

Nice to know...
or **NEED** to know?

Time to
EVALUATE

Amended Regulations on micro-organisms: need to know approach

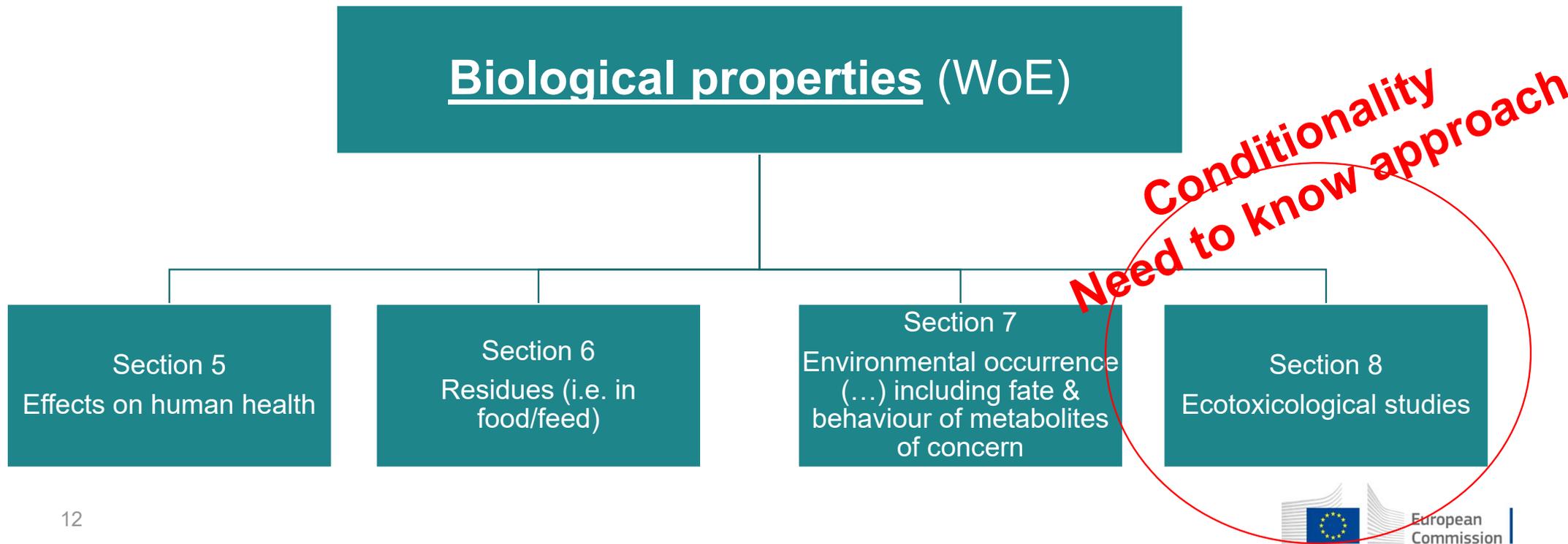
- data requirements active substances
- data requirements plant protection products
- Uniform principles
- Decision making criteria (Annex II)

Applicable from 21 November 2022!

For active substance dossiers (IUCLID):

- Voluntary to the applicant until **21 May 2023**
- Compulsory to the applicant from **21 May 2023**

- biological properties **central role** in data requirements



Implementation Regulations 283/2013 and 284/2013

Data requirements for active substances and plant protection products*

1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such **information shall not be required**, where one of the following conditions is fulfilled:

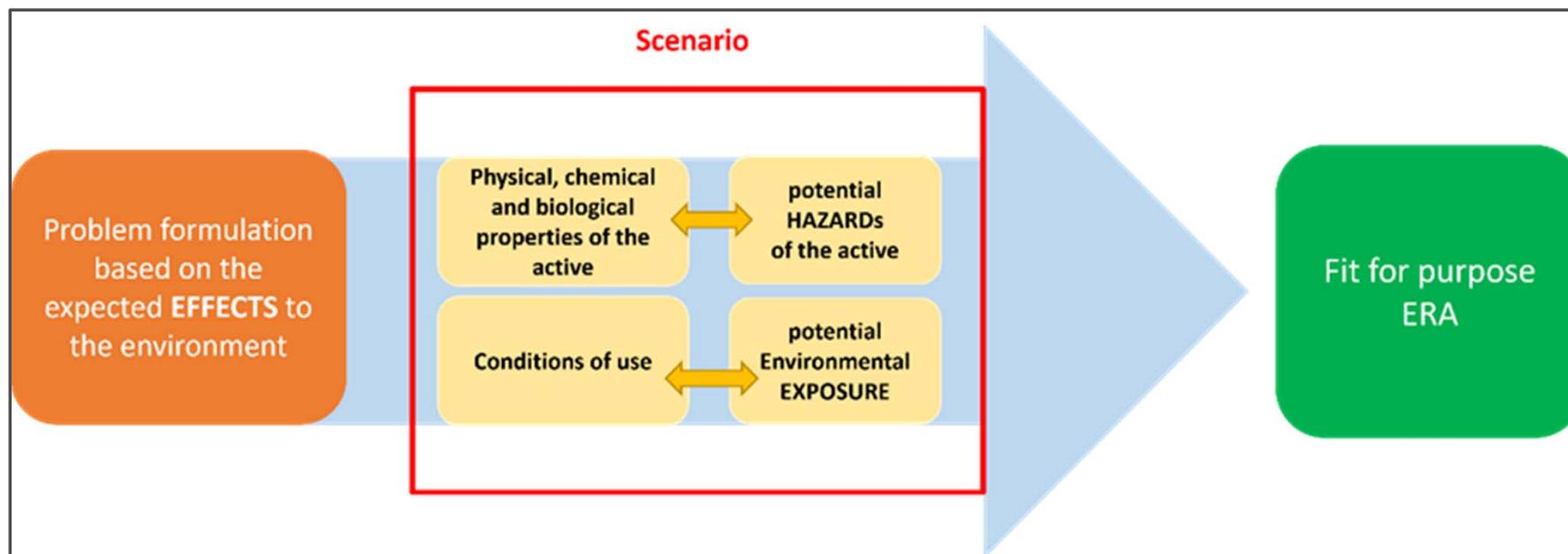
- (a) it is not necessary **owing to the nature of the product or its proposed uses**, or it is not scientifically necessary;
- (b) it is technically not possible to supply.
- In such a case **a justification shall be provided**.

Need to know approach

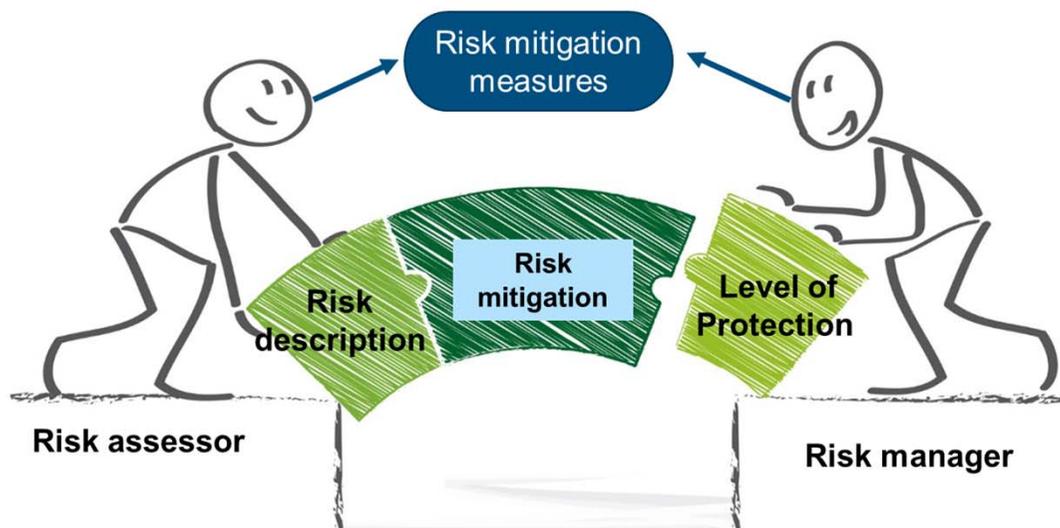


draft problem formulation document

Aim of PF document: strengthen problem formulation of ERA for the approval of AS at the EU level (pre-submission meetings!)



Role of pesticide application techniques / conditions of use in the regulatory process



Pesticide application technique and conditions of use considered at RA (representative use/ GAP description) and/or at RM level

Application conditions / Risk Mitigation Measures

- List (“compendium”) of technical use and application conditions for PPP
 - Discussions on-going at the WG on environmental relevant topics
→ draft in preparation

To solve: not all “technical measures” have a well characterised exposure reduction factor – data are needed for validation/ harmonisation!



Take home messages from a risk manager

- Guidance documents facilitate RA (i.e. agreement on methods), but may not cover all situations
 - Keep in mind the particular situation to be evaluated: „standard“ vs. „ad-hoc“ cases
 - Keep in mind „need to know“ approach
- GD are/ need to be continuously updated (scientific progress)
 - „generic“ robust data are needed for drafting and updating guidance documents

