Independence of scientific data and risk assessments for decision making based on evidence

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Workshop Harmonised Human Health RA of PPPs
23 – 24 November 2017, Berlin

Outline

- *Scientific data & risk assessment*
- *Regulating PPPs in the EU: where do we stand?*
- *Looking into the future: next steps*

Scientific data

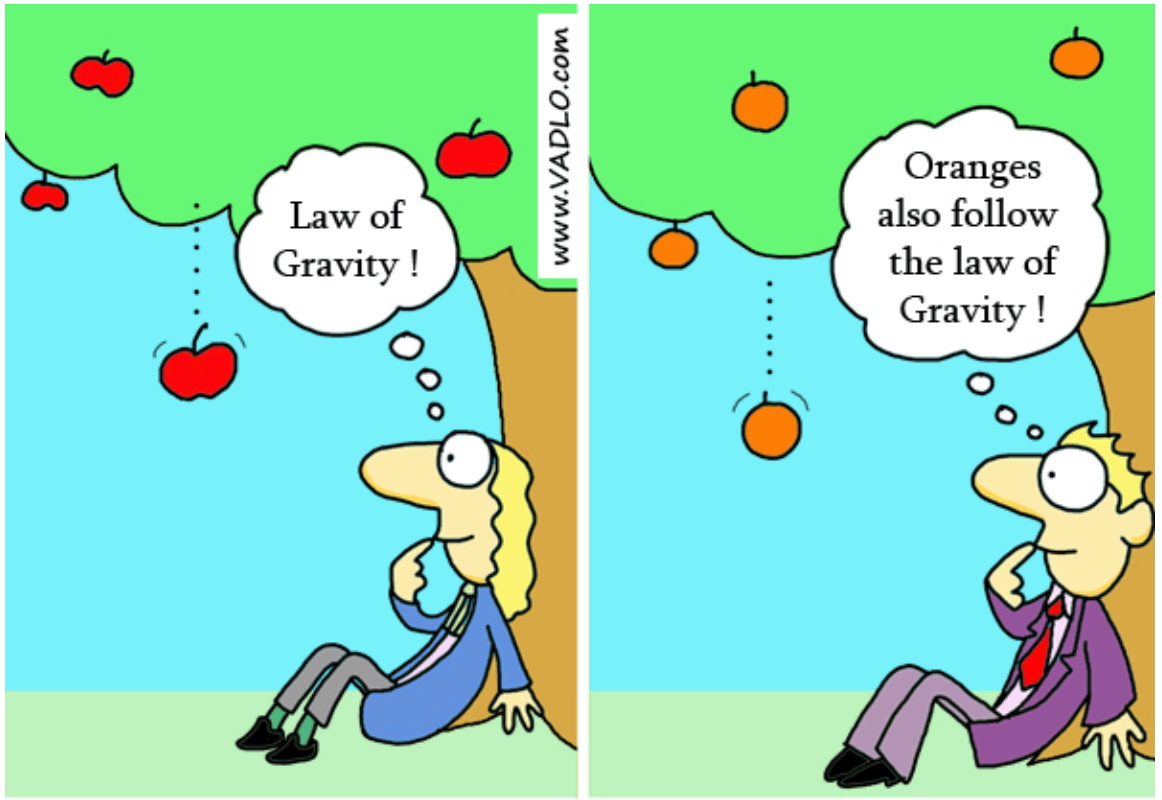
GENERATION PHASE

Research - collection of raw data with a method (construct & test a hypothesis)

REPORTING / PUBLICATION PHASE

context (introduction), material & method, results, conclusions

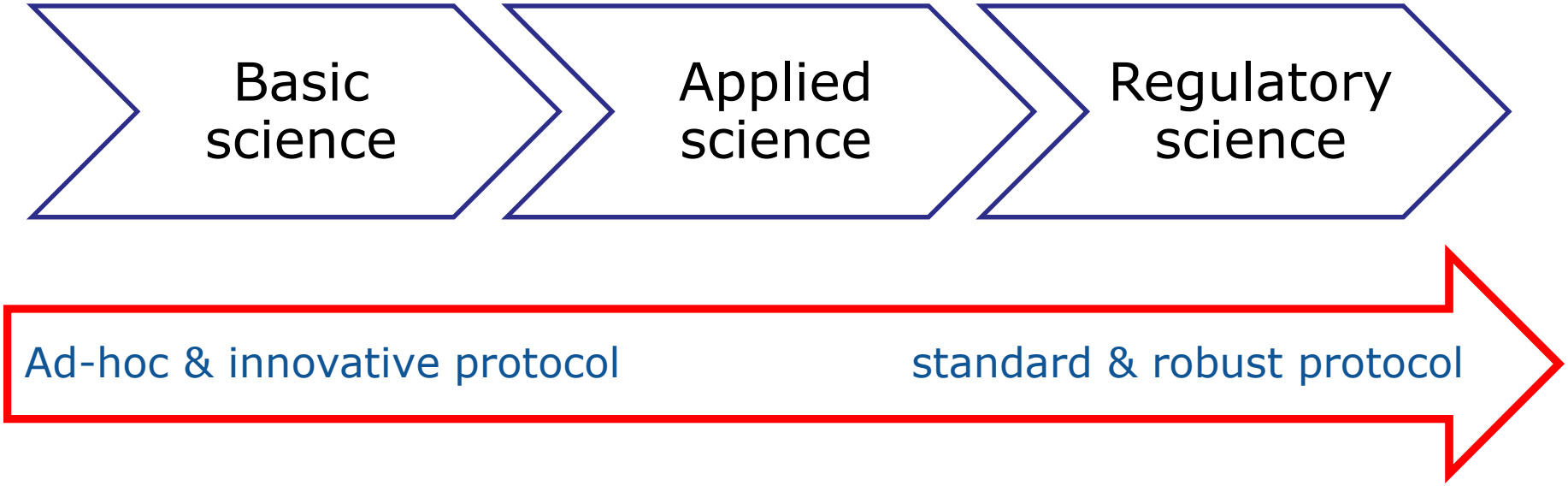
Scientific Data are variable



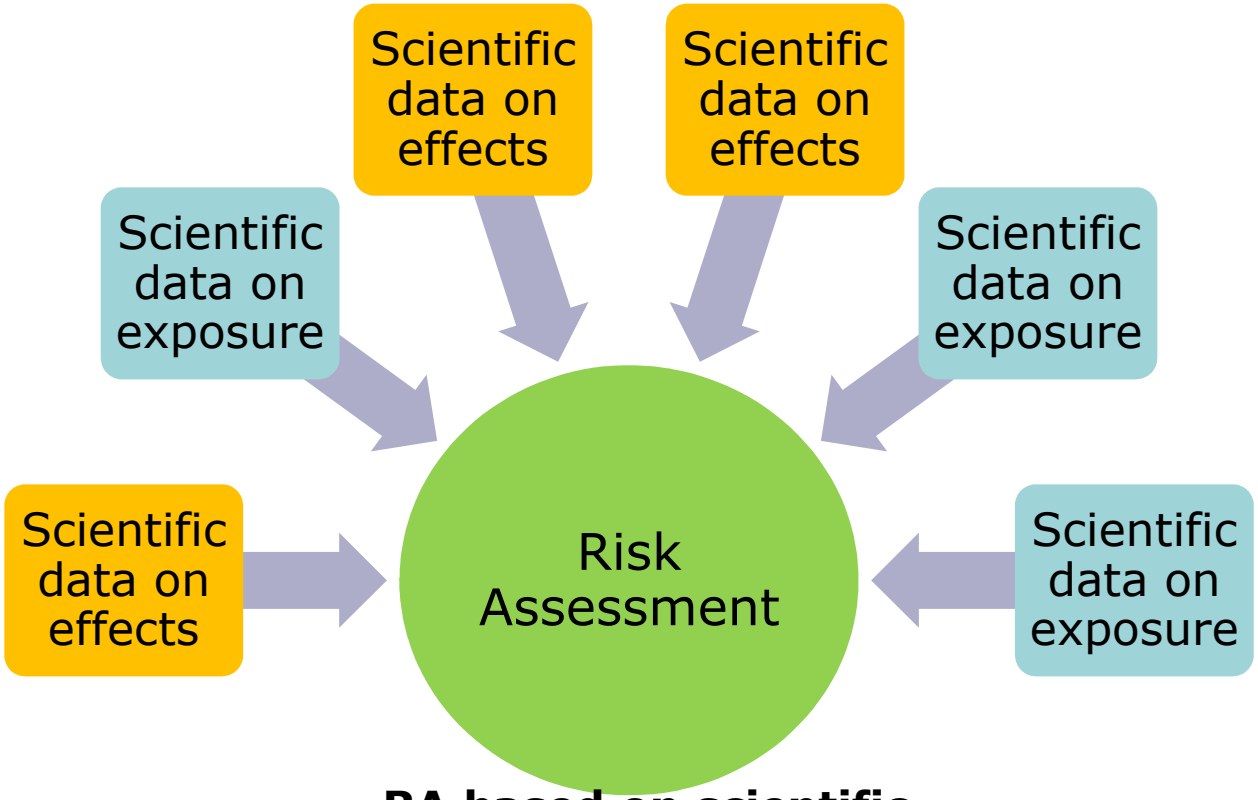
High Impact Paper

Low Impact Paper

Scientific Data are variable



Risk Assessment is based on science



RA based on scientific guidance documents

Generation of scientific data and carrying out RA is highly complex

→ needs high level of expertise

→ **resource intensive:**

- building up expertise
- data generation
- RA and evaluation

→ *somebody needs to provide funding*

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Regulation of PPPs in the EU

Directive 91/414/EEC → Regulation (EC) No 1107/2009

Principles:

- "polluter pays"
- positive list of active substance

→ ***Burden to applicant*** *to demonstrate that the active substance can be used in a way that*

→ *poses no risks to HH or animal health,*

→ *nor any unacceptable effect on environment*

Scientific data needed for the Regulation of PPPs in the EU

Directive 91/414/EEC	Regulation (EC) No 1107/2009
Data requirements • international study protocols (e.g. OECD protocols) • Ad-hoc studies • GLP requested	Revised data requirements which are regularly updated • international study protocols (e.g. OECD protocols) • Ad-hoc studies • GLP requested • Peer reviewed literature (Art 8.5 & systematic review GD EFSA)
Uniform principles	Uniform principles
guidelines	New and updated guidelines (EFSA)

Why standard study protocols?

… because they …

1. *set the **same scientific data requirements** to all substances → same ways of generating data allow assessing all substances with a common approach*
2. *are **robust**, results have been proven reproducible and reliable after ring-testing*
3. ***evolve ("open list")**: continuous on-going process to validate new study protocols or update existing protocols to latest science*

*…In addition, **supplementary studies** (case by case need and design) may need to be provided …*

Why good laboratory practice (GLP)?

… because GLP implies…

- *an **independent** quality assurance system*
  - **implies that the reports reflect the raw data collected**
- *full **traceability** of each study*
  - **from conception to report, use and dosage of the substances, to reporting and archiving**
- ***archiving** of all information of each study for a period fixed by the authorities (usually 10-15 years)*
  - **retroactive inspection possible**
- *For each GLP facility, a **list of GLP studies** conducted at this facility*

What is GLP?

*GLP is a quality standard which focus on **how the work** is organised (not on the scientific quality of the protocols)*

- *Facilities are GLP-certified by MS authorities*
  - **for specific areas of expertise**
  - **GLP certification is regularly checked ("risk based" inspections)**
- *GLP compliance implies setting up robust working processes (resource intensive)*
- *GLP compliance implies separation of responsibilities: conducting a study, quality assurance, and general management*

GLP EU-legislation

DIRECTIVE 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles GLP and the verification of their applications for tests on chemical substances

DIRECTIVE 2004/9/EC on the inspection and verification of good laboratory practice (GLP)

→ follow OECD principles

GLP – milestones at OECD

- **1978** - the OECD Principles of GLP were developed by an Expert Group established in under the Special Programme on the Control of Chemicals
- **1981/83** - OECD Council recommends those Principles of GLP for use in Member countries
- **1998** - revised OECD Principles of GLP

Peer reviewed literature

- *Primary literature (basic and applied experimental research)*
- *Secondary literature (reviews)*

- *Reporting quality and availability of **raw data** is variable, archiving and traceability of raw data is not standardised in peer review process*
- *Variable **authorship**: one or several authors / affiliations*
- ***Funding** is variable, could be mixed, is not always transparently reported*

Peer reviewed literature

Systematic review methodology is crucial

Transparent, robust, objective and reliable process

- *To identify all relevant information: primary literature (secondary literature rather not relevant)*
- *for assessing the identified peer reviewed literature*

Risk Assessment - context

Risk Assessment

- *Based on **scientific evidence***
- ***Peer review process**: all MS involved, EFSA coordinates the process*
- ***Separation risk assessment and risk management** (GFL & Reg 1107/2009) is crucial, but RA needs to be suited to the RM (RA and RM follow a common objective set in the legislation)*
- ***Independent agencies** (EFSA) with robust system for selecting experts based on declaration of interest*
- ***Uniform principles & agreed guidelines** contribute to an agreed independent approach*

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Next steps

1. *REFIT - Regulatory Fitness and Performance programme - Evaluation of the EU legislation on PPPs and pesticides residues*
2. *Scientific Advice Mechanism (European Commission, Research & Innovation)*
3. *European Citizens Initiative*

European Citizens Initiative

- registration 25/01/2017, more than 1 million signatures of citizens (from minimum 7 MS crossing their respective thresholds)
- Requests to "*…ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry…*"
- Formal acceptance 06/10/2017 (after verification by MS)
- reply of COM by 08/01/2018

http://ec.europa.eu/citizens-initiative/public/welcome

Scientific Advice Mechanism (SAM)

(European Commission, Research & Innovation)

- Authorisation processes of PPPs in Europe, could the current EU dual system for approval and authorisation of PPPs rendered more effective, efficient and transparent, and if so, how?

https://ec.europa.eu/research/sam/index.cfm?pg=pesticides

REFIT - Evaluation of the EU legislation on PPPs and pesticides residues

- Regulatory Fitness and Performance programme (REFIT) is a rolling programme to keep the EU legislation under review and ensure that it is 'fit for purpose',
  - that regulatory burdens are minimised and
  - that all simplification options are identified and applied.
- The evaluation process includes different steps and is foreseen to be finalised in the first half of 2019.
- Transparent process: https://ec.europa.eu/food/plant/pesticides/refit_en

REFIT: on-going evaluation and consultations

- **public consultation** open until 12 Feb 2018 (addressed to citizens, in all EU languages)
- **stakeholder survey** open until 31 Dec 2017 (addressed to stakeholder incl. academia and 3rd countries, EN only)
- **survey to SME** open until 15 Jan 2018 (all EU languages)
- **survey to Member State Competent Authorities** sent out, deadline 31 Dec 2017

→ study carried out by an external contractor

REFIT: Structure of the stakeholder questionnaire

136 Q – but …. All questions are non-mandatory. *No need to answer all of the questions for a contribution to be taken into account.*

1) General perception of the Regulations

2) The PPP Regulation - *Regulation (EC) No 1107/2009*

- Implementation and enforcement
- Definitions
- Approval of active substances
- Authorisation of plant protection products
- Comparative assessment of Candidates for Substitution
- Availability of plant protection products
- Timelines and time-limited approval periods
- Costs and benefits
- **Submission of data, transparency, and public consultation**
- **Testing and data sharing**

3) The MRL Regulation *- Regulation (EC) No 396/2005*

4) Additional comments

Stakeholder questionnaire: Q on scientific data - examples

- *Are the existing **provisions flexible enough** to take new scientific information into account …?*
- *How has the PPP Regulation impacted the development of studies involving **vertebrate animal testing** …?*
- *For the approval of an AS and the authorisation of a PPP, applicants have to provide a dossier of documents and studies that provide evidence on the hazards and risks. Do you think that this procedure may negatively affect the **objectivity** of the dossier?*
- *Do you believe there are sufficient **opportunities for the scientific community and civil society to contribute** during the decision-making process?*

Open fields after several questions and at the end of the survey. Position papers also welcome.

REFIT - on-going evaluation and consultations (PPPs)

Other activities planned… Keep updated …

https://ec.europa.eu/food/plant/pesticides/refit_en

Take home message

Independence of scientific data and risk assessments for decision making based on evidence …

- *stands on a robust system established in 1991,*
- *which was improved in 2009.*
- *A REFIT evaluation is initiated.*