Amendments of EU regulation of micro-organisms used in plant protection products

SANTE E4

Domenico Deserio, Eric Liégeois

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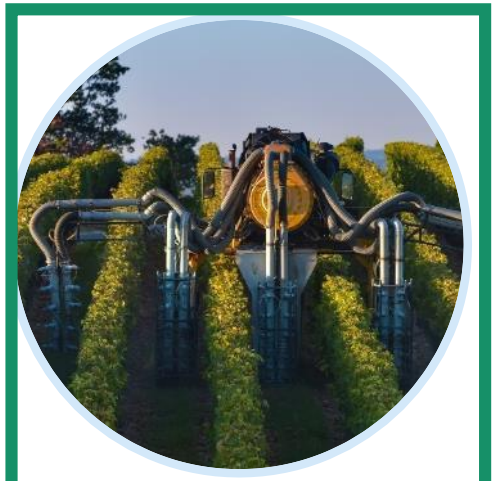
Regulations concerned
Six texts applying on micro-organisms (MO)

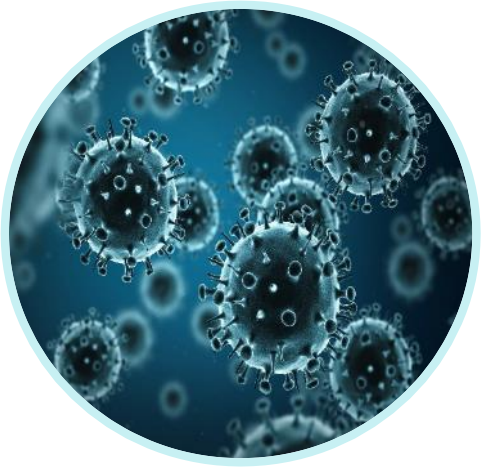
- Amendments of:
  1. ***data requirements*** *for* ***active substances*** *(AS)*
  2. ***data requirements*** *for* ***plant protection products*** *(PPP)*
  3. ***uniform principles*** *for* ***evaluation/authorisation*** *of PPP*
  4. ***Annex II*** *to Regulation (EC) No* ***1107/2009 approval criteria*** *of microbial AS*
- New:
  5. ***Commission Communication*** *on test methods and guidance documents for* ***AS***
  6. ***Commission Communication*** *on test methods and guidance documents for* ***PPP***

2030 Farm to Fork Targets



Reduce by 50% the overall use and risk of **chemical pesticides** and reduce use by 50% of more hazardous **pesticides**

Reduce **nutrient losses** by at least 50% while ensuring no deterioration in soil fertility; this will reduce use of **fertilisers** by at least 20 %



Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%

Achieve at least 25% of the EU's agricultural land under **organic farming** and a significant increase in **organic aquaculture**

European Commission

Principles of the revision

- New scientific approaches:
  - ✓ MO are intrinsically different from chemicals, so they deserves a specific approach!
  - ✓ We know more about MO: science evolved, technology offers new opportunity
  - ✓ AIR program: more “fresh” experience with “real-life” dossiers
  - ✓ Weight of evidence

- Be good at the first time (dossiers’ quality)
  - ✓ “Need-to-know” approach (i.e. which questions are we trying to answer?)
  - ✓ More emphasis on request to justify missing data

- Tiered-based approach (mandatory and conditional requirements)

Revision of concerned Regulations
Milestones

The Biopesticides Working Group!

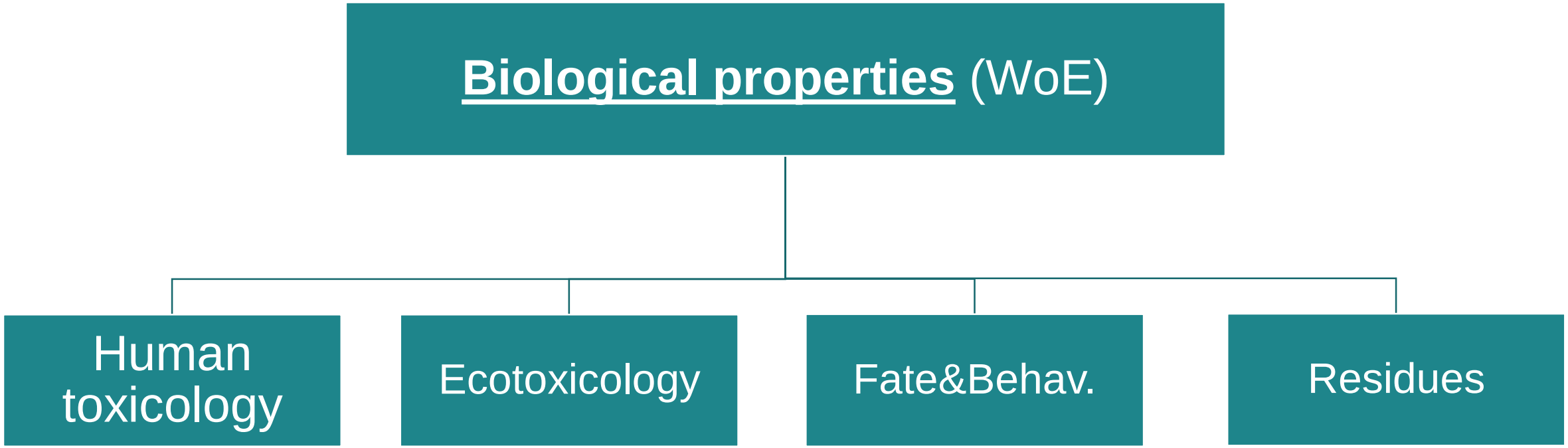
Q4 2018 Q3 2019	Q4 2019 Q3 2020	Q4 2020 Q1 2021	Q2-Q4 2021	Q4 2021 Q1 2022	Q1/Q2 2022	Oct 2022
Identify issues of the current Regulations	Drafting the 4 Regulations	First PAFF[1] Committee consultation	ISC[2], stakeholders	PAFF Committee vote	Formal adoption process (EP and Council)	Entry into applicability + IUCLID

Today

1: Standing Committee Plant, Animal, Food and Feed
2: interservice consultation

Biological properties

- Central role in data requirements, information for weight of evidence (WoE) approach – connection with other sections



Biological properties

- *e.g.* "Growth requirement" on biological properties to support WoE in human tox
- Clear separation between:

  ✓ presence of antimicrobial resistance (AMR)

  genotype,

  ✓ possibility of AMR to be transferred, and

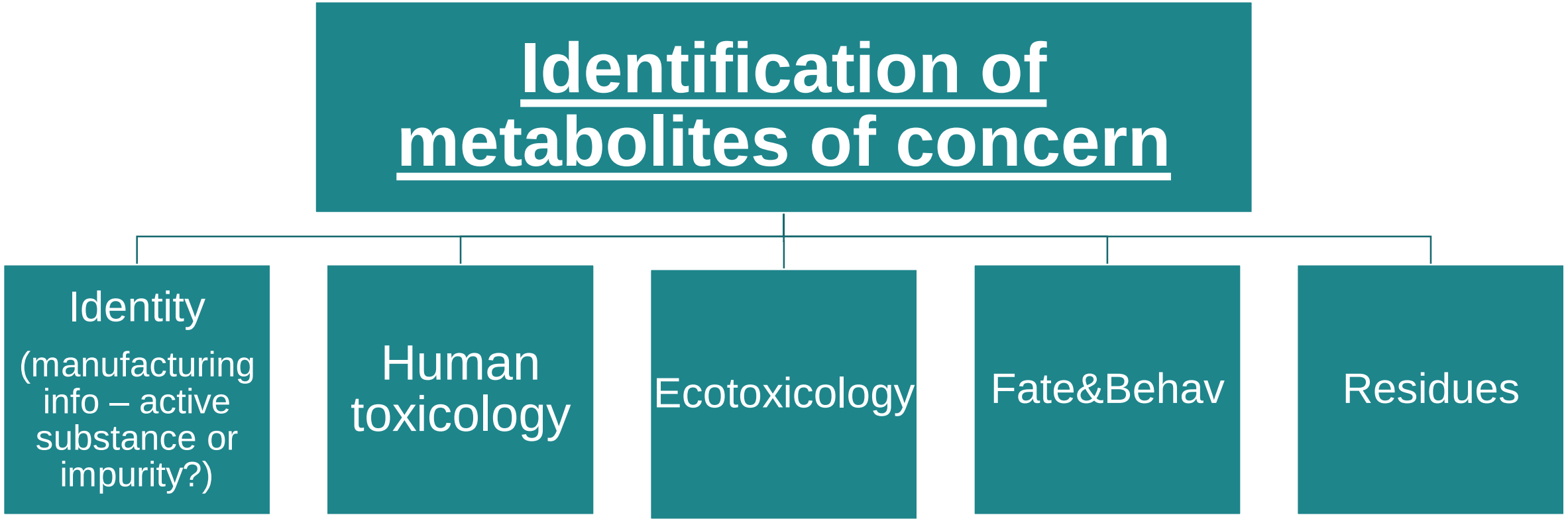
  ✓ treatment options (*i.e.* this in human tox. section).

- **Guidance document**
- **Only relevant antimicrobial agents (*e.g.* Regulation (EC) No 2019/6* or WHO definition)**

* Reg (EU) 2019/6 on veterinary medicinal products (OJ L 4, 7. 1.2019, p.43)

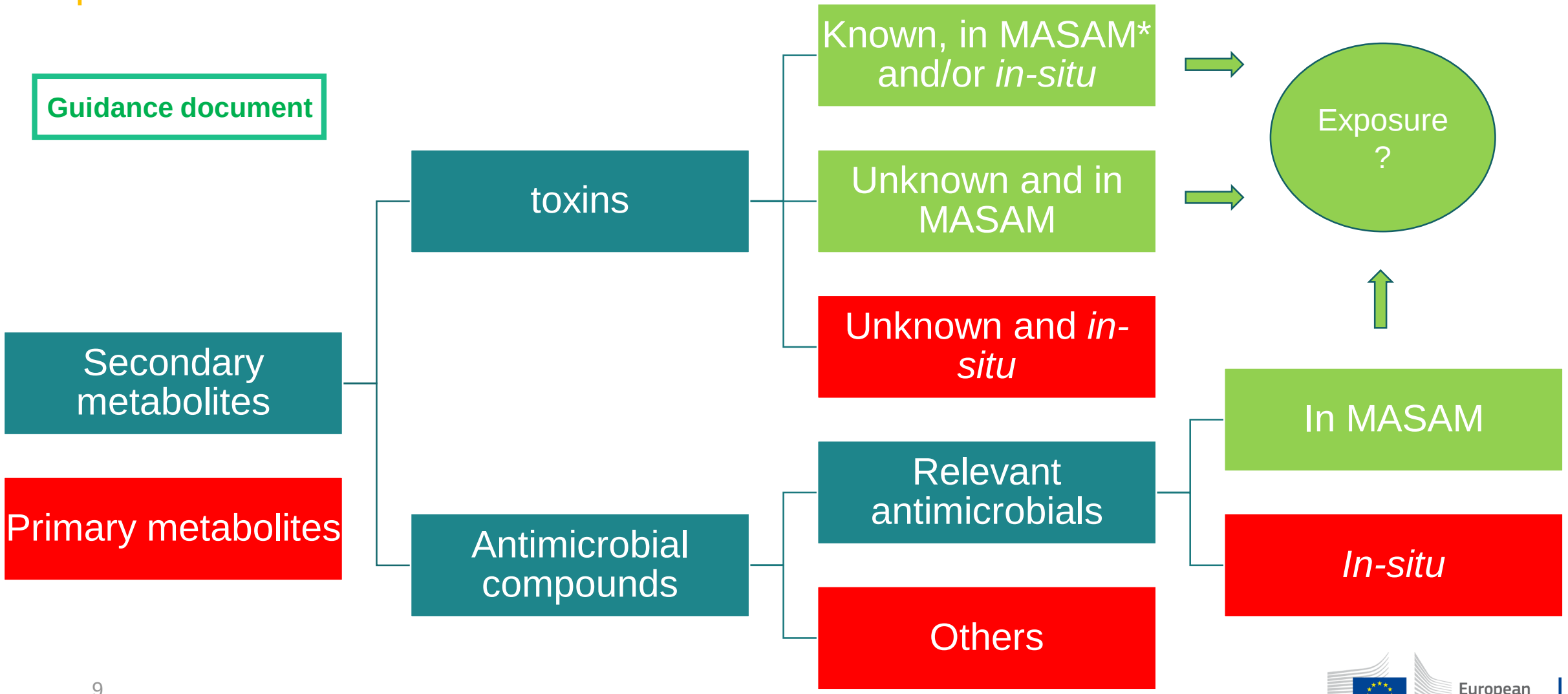
Biological properties

Identification of metabolites of concern – connection with other sections



Biological properties

Identification of metabolites of concern – relevant ones



*MASAM: Microbial Active Substance as Manufactured

Effects on human health

Human toxicity of metabolites of concern

1- Were metabolites of concern identified (human dietary and non-dietary exposure)?

- Possible identification in biological properties

No more data

2- Setting toxicological reference values

- Is it possible to set tox reference values based on data available in biological properties?

No more data

3- Data generation

- Possibly required on a case-by-case basis (reference to Part A of data requirements for chemical AS)

Effects on human health

Human pathogenicity of micro-organisms

1- Weight of evidence approach

- Biological properties (e.g. occurrence, history of use, MoA, host specificity, growth requirements, relationship with known pathogens, infectiveness)
- Medical data (e.g. surveillance, direct observation)
- Others (e.g. peer-reviewed literature, Qualified Presumption of Safety)

No more data

2- Pathogenicity and infectivity studies (new data generation)

- Acute oral, and/or
- Acute intratracheal/ intranasal, and/or
- Intravenous/Intraperitoneal or subcutaneous test

No more data

3- Specific pathogenicity and infectivity studies (new data generation)

- If WoE and Pathogenicity and infectivity studies require further investigation

Effects on human health

Only toxicity studies (no pathogenicity)

1- Weight of evidence approach

- Physical, chemical, technical properties, data on application, others (e.g. CLP calculation rules)

No more data

2- Toxicity studies

- Acute oral, and/or
- Acute dermal, and/or
- Acute inhalation
- Skin irritation
- Eye irritation
- Skin sensitisation

No more data

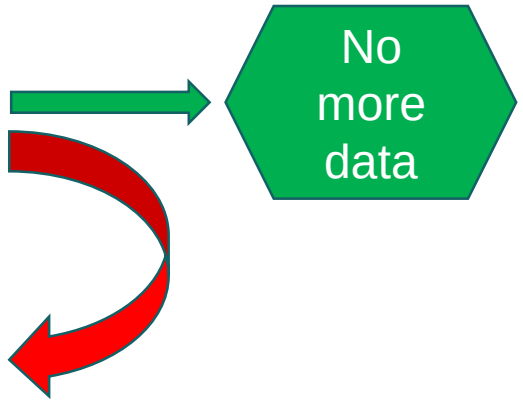
3- Additional studies

- If further investigation as required

Residues
Fate & Behaviour

1- Extrapolation of existing data

- Extrapolation for PPP possible by using data submitted for AS?



2- Data generation

- Same dataset described in Reg. 283/2013

Approval criteria and uniform principles

- Annex II to Reg. 1107/2009, approval criteria:
  - No new criteria, but specification for micro-organisms on Art 4 Reg 1107/2009 (e.g. human pathogenicity, AMR transfer)
  - Low risk criteria
- Reg. 546/2011 (Uniform Principles) evaluation + decision-making for PPP:
  - Adaptation to new data requirements

To sum-up

- Need-to-know approach: no unnecessary studies, maximal use of available information regarding biology
- Tiered-based approach: if data/results identify a concern, assessment continues, otherwise ‘stop’ (!)
- Key techniques (e.g. genomics) helpful for waiving possible questions on AMR, metabolites, etc…
- Have your say: https://ec.europa.eu/food/horizontal-topics/consultations-and-feedback_en#consultations

Keep in touch

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