Plant protection products – update and ongoing developments

PLENARY MEETING

ADVISORY GROUP ON THE FOOD CHAIN AND ANIMAL AND PLANT HEALTH

7 MAY 2021, VIRTUAL MEETING

Karin Nienstedt, Domenico Deserio - DG SANTE

Outline

- Transparency Regulation Implementation
- Guidance Documents & mandates to EFSA
- Updates on implementing acts for microorganism used as active substances in PPPs

Implementing Regulation (EU) 2020/1740 repealing Commission Implementing Regulation (EU) No 844/2012

- applies from 27 March 2021 (AS which expire on or after 27 March 2024, Art 17 extensions are excluded)

- Key Changes:
  - ✓ Pre-submission phase – including notification of studies
  - ✓ Single step – submission of a renewal application 3 years before expiry
  - ✓ Dossier submission via IUCLID (no CADDY dossiers)
  - ✓ Contents of the renewal dossier more comprehensive
  - ✓ Full dossier published
  - ✓ Public consultation on the dossier
  - ✓ New window for applicants (2 weeks) for submission of information at the end of the peer review (comments on the draft EFSA Conclusion)
    - ✓ Critical issues leading to no safe use which the applicant could not foresee or had no opportunity to address during the stop the clock

Impact on the Renewal Programmes

- Some substances in AIR4 and the majority in AIR5 fall under the new rules whereas all substances in AIR3 remain under Regulation 844/2012

- Consideration of the impact on substances that fall under the new rules was undertaken with a view to avoiding significant changes to dossier submission dates in 2021

- Implementing Regulation (EU) 2020/2007 was adopted on 8 December 2020 – extends the approval periods of 54 substances

- The work programmes on the **public webpages have been updated** and clearly indicate which rules apply and the dates for submission.

What else?

- Dossier submission via IUCLID for new active substances and amendments of conditions of approval (Implementing Regulation (EU) 2021/428)
- Updated Guidance for Basic Substances & submission via IUCLID (April 2020)
- Administrative Guidance EFSA - including MRLs
- EFSA’s Practical Arrangements
- Europa webpages updated

Outline

- Transparency Regulation Implementation
- **Guidance Documents & mandates to EFSA**
- Updates on implementing acts for microorganism used as active substances in PPPs

New / updated GD endorsed by PAFF…

- GDs on secondary metabolites (micro-organisms)
- GD on anti microbial resistance (micro-organisms)
- GD on time dependent sorption of pesticides in soil (Aged sorption for groundwater leaching)
- Update of GD on emergency authorisations
- EFSA GD on isomers
- *On-going: update GD on relevance of groundwater metabolites (update to align genotox part, major update planned later)*

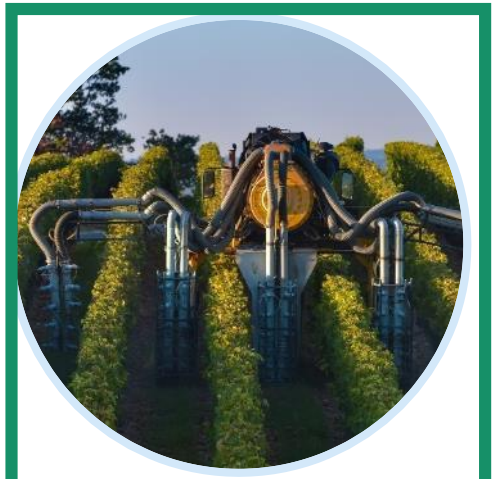
EFSA mandates…

- Mandate to EFSA and ECHA to develop GD on impact of water treatment processes to residues of AS or metabolites
- Mandate to EFSA to review bee GD
- Mandate on EA neonicotinoids
- Mandate on Art 69/71 (acetamiprid and flupiradifurone)
- *In preparation:*
  - mandate on azole resistance of *Aspergillus* spp. (*A. fumigatus*)
  - Mandate on groundwater monitoring studies and its use in RA

Outline

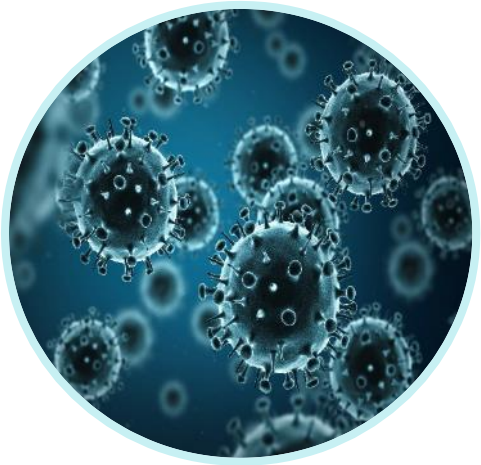
- Transparency Regulation Implementation
- Guidance Documents & mandates to EFSA
- Updates on implementing acts for microorganism used as active substances in PPPs

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 %

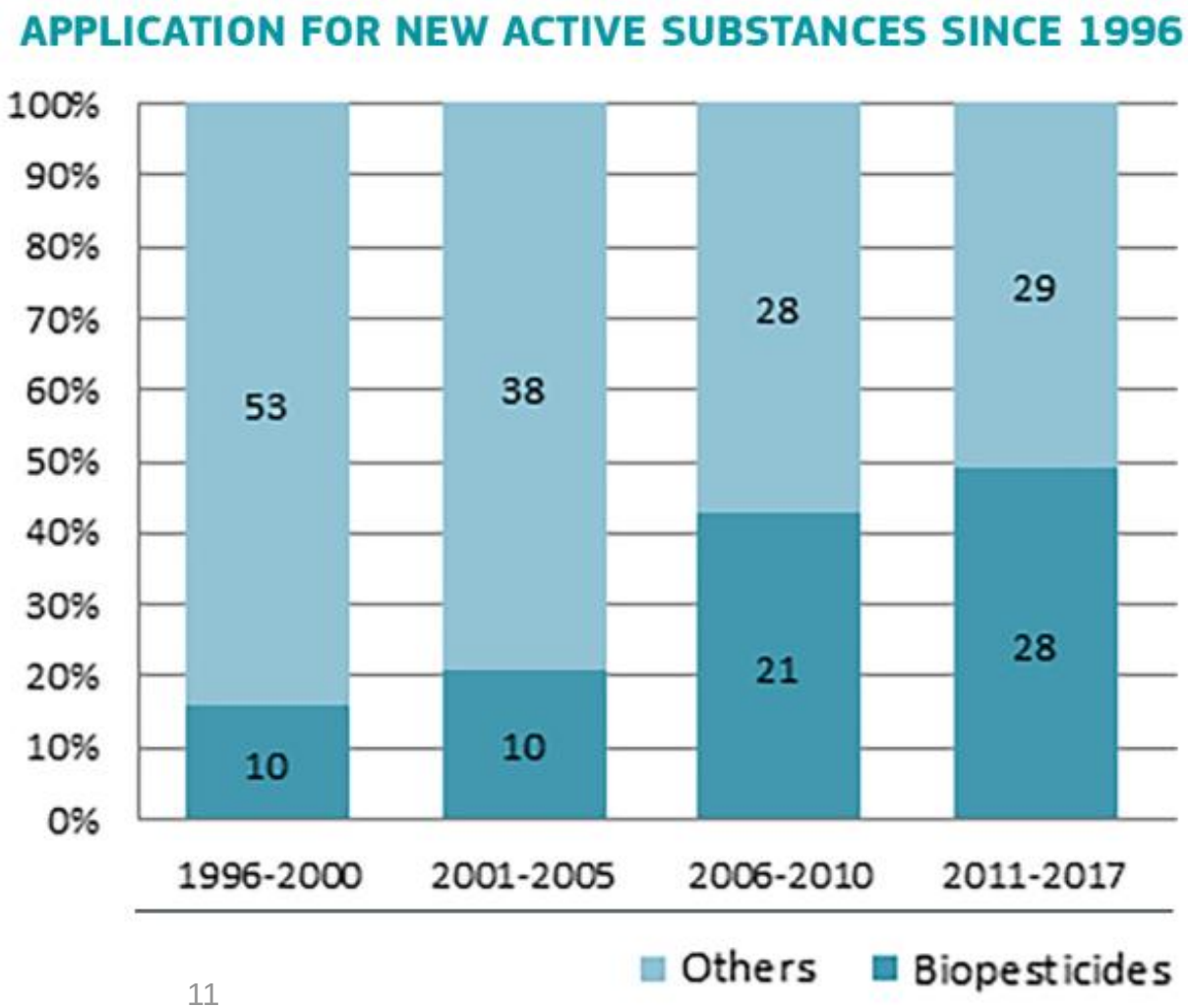


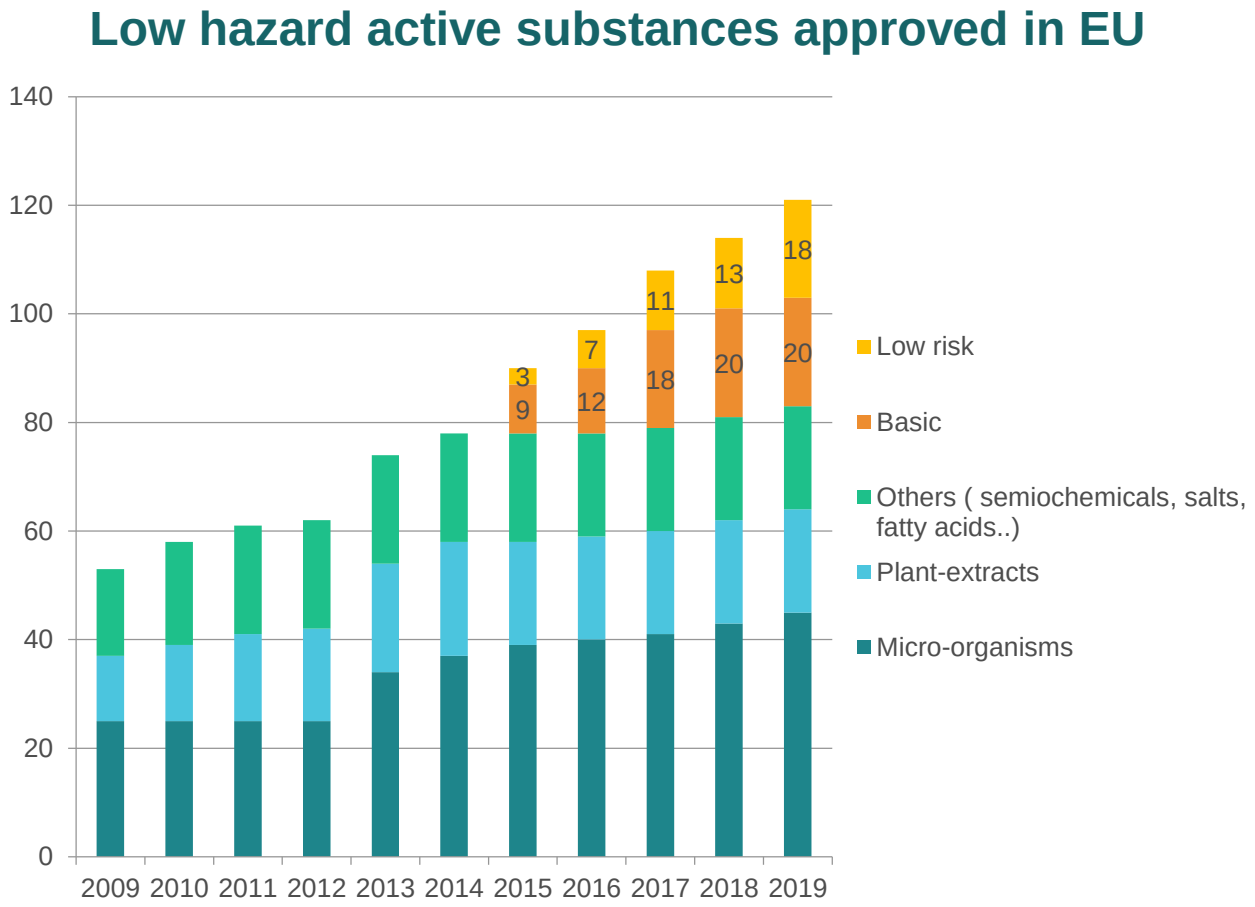
Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%

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

European Commission

Why focusing on micro-organisms?





European Commission

Aim of the revision

- Six texts 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***

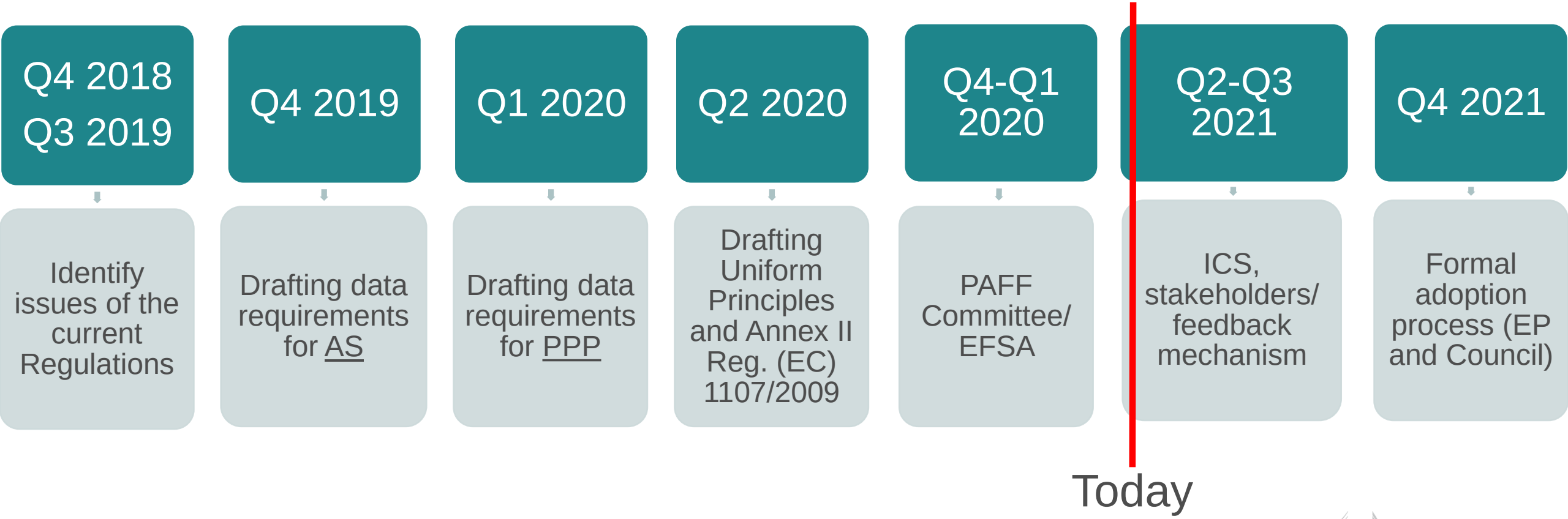
Principles of the revision

- New scientific approaches:
  - ✓ Stop mimicking chemical approach!
  - ✓ Evolution of science and technology
  - ✓ Experience with current applications
  - ✓ 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



European Commission

Amendments of:

1. Data requirements for AS (Reg. 283/2013)
2. Data requirements for PPP (Reg. 284/2013)
3. Uniform principles (Reg. 546/2011)
4. Annex II to Regulation (EC) No 1107/2009

New:

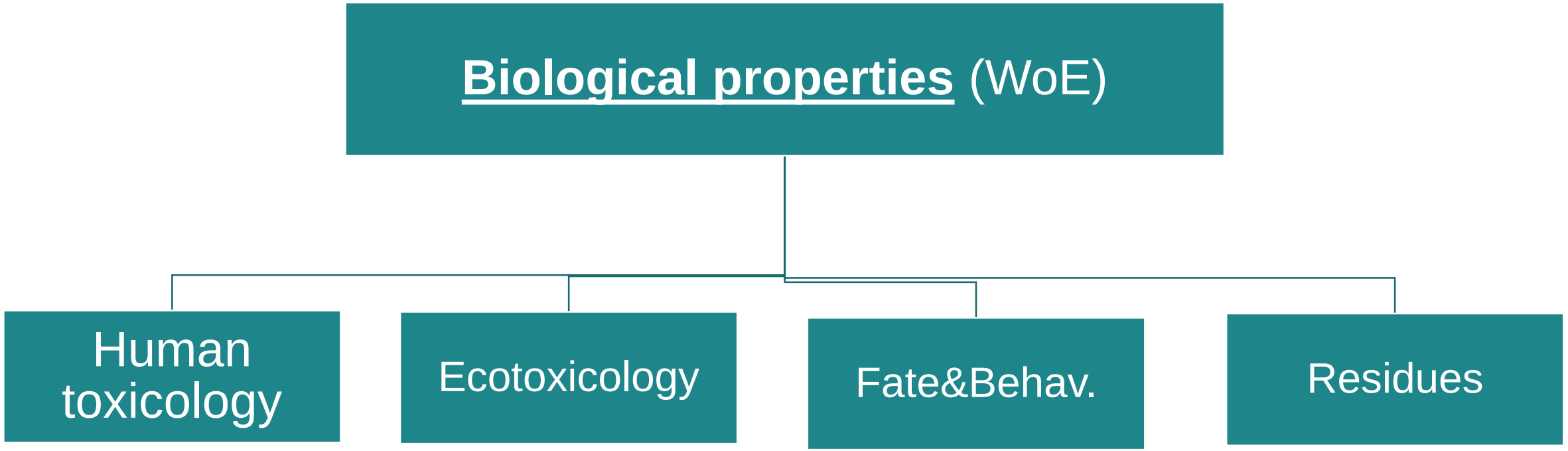
5. EC Communication for AS
6. EC Communication for PPP

1- Identity of the applicant, the microbiological active substance, and manufacturing information

- Micro-organism (MO):
  - ✓ identified as unequivocally belonging to a certain species,
  - ✓ named at strain level, including other designation if relevant e.g. isolate for viruses
  - ✓ phylogenetic tree
- Content of the active substance:
  - ✓MO in appropriate MO units
  - ✓ May include metabolites of concern

2- Biological properties

- Central role in data requirements, information for weight of evidence (WoE) approach



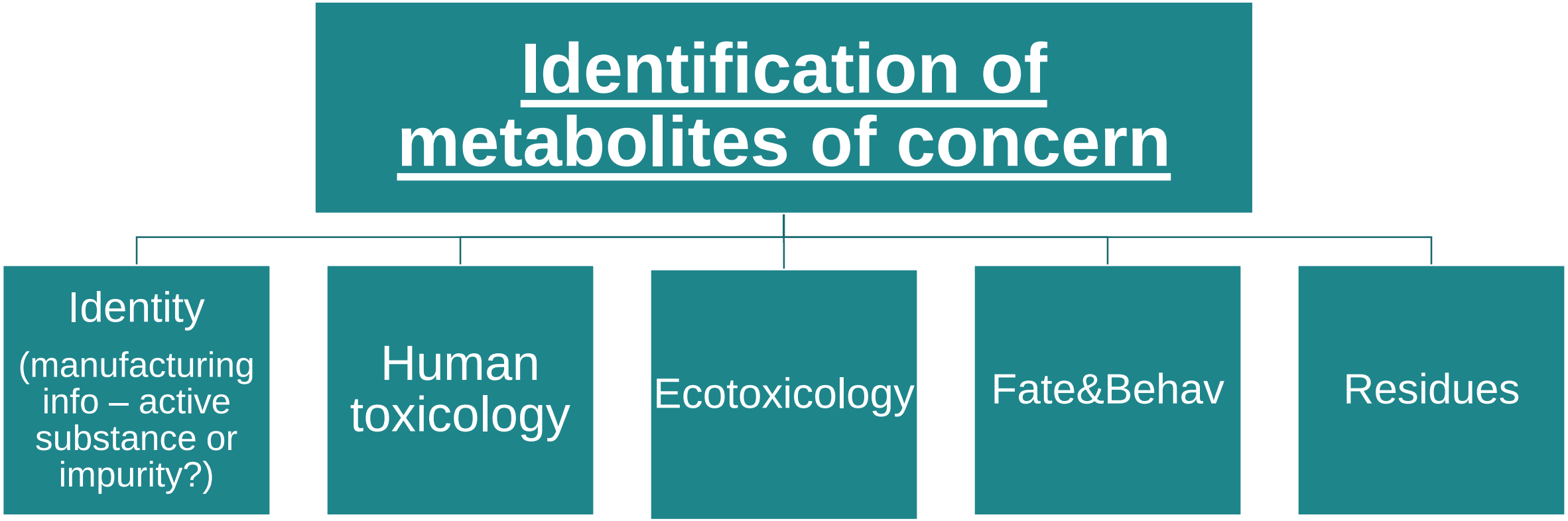
2- Biological properties

- *e.g.* “Growth requirement” on biological properties to support WoE in human tox
- Clear separation between:
  - ✓ presence of antimicrobial resistance (AMR),
  - ✓ possibility of AMR to be transferred, and
  - ✓ treatment options (*i.e.* this in human tox. section).

- **Guidance document**
- **Only Medically Important Antimicrobial (*i.e.* WHO definition)**

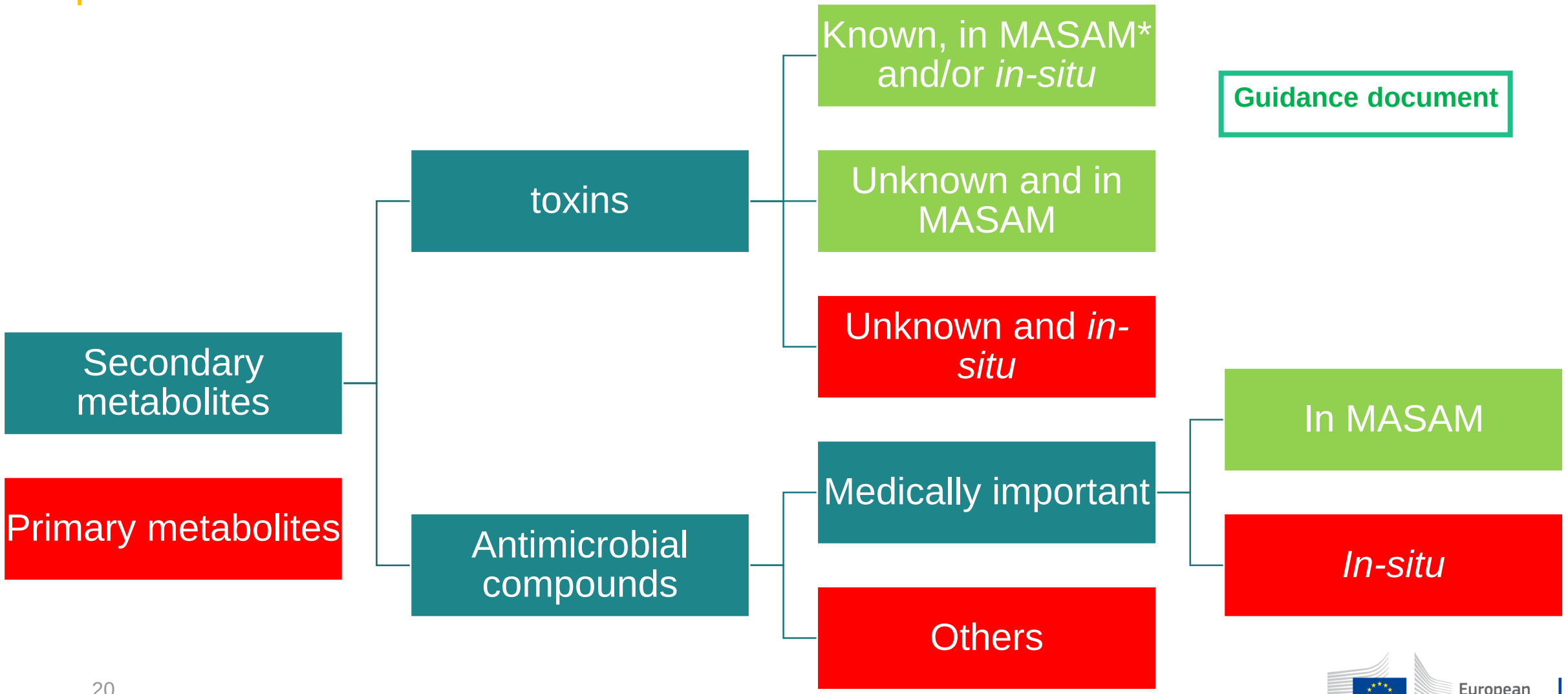
2- Biological properties

Identification of metabolites of concern – connection with other sections



2- Biological properties

Identification of metabolites of concern – which are relevant?



Guidance document

European Commission

*MASAM: Microbial Active Substance as Manufactured

5- Effects on human health

WoE and pathogenicity tests

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)

STOP

2- Pathogenicity and infectivity studies (new data generation)

- Oral, and/or
- Intratracheal/ intranasal, and/or
- Intravenous/Intraperitoneal or subcutaneous test

STOP

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

- If WoE and Pathogenicity and infectivity studies require further investigation

5- 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

STOP

2- Setting toxicological reference values

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

STOP

3- Data generation

- Possibly required on a case-by-case basis

6 Residues

Were metabolites of concern identified (human dietary exposure)?

- Possible identification in biological properties
- There should be no concerns on pathogenicity of MO!

STOP

Estimation of consumer exposure to residues

- Based on worst-case scenario, intended use, MO biological properties, production and properties of the metabolite
- Direct measurements of metabolites of MO may support

STOP

Data generation on residue

- If more metabolites of concern reach this stage, they can be tested together (*e.g.* using the PPP)

7 Fate & Behaviour

Supports exposure assessment for each NTO

1- Qualitative assessment/ modelling

- Intended use, biological properties, PED, PEC

STOP

2- Quantitative assessment

- Measurement of MO density and/or metabolites of concern in relevant compartment (before and after application)

STOP

3- Studies on NTO

- Test MO pathogenicity/infectivity to the NTO?
- Literature data accepted

8 – Ecotoxicology

Pathogenicity studies on MO

Summary on pathogenicity and infectivity

- Information already provided in "biological properties" mainly (but also others)
- Does this summary allow to conclude on pathogenicity/infectivity?

STOP

Assessment of exposure

- Is exposure to the NTO absent based on information provided in F&B?
- *n.b.* it may be different for vertebrates

STOP

Additional studies

- Possibly required

8 – Ecotoxicology

Toxicity studies on metabolites of concern

1- Were metabolites of concern for non-target organisms identified?

- Possible identification in biological properties

STOP

2- Setting toxicological reference values

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

STOP

3- Data generation

- Possibly required

Amendments of:

1. Data requirements for AS (Reg. 283/2013)
2. Data requirements for PPP (Reg. 284/2013)
3. Uniform principles (Reg. 546/2011)
4. Annex II to Regulation (EC) No 1107/2009

New:

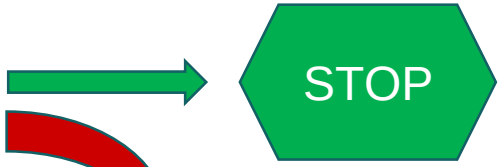
5. EC Communication for AS
6. EC Communication for PPP

7- Effects on human health

Only toxicity studies (no pathogenicity)

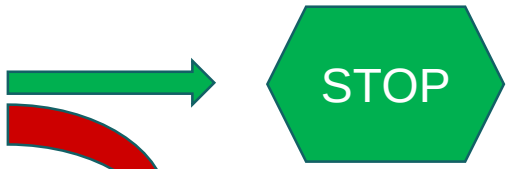
1- Weight of evidence approach

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



2- Toxicity studies

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



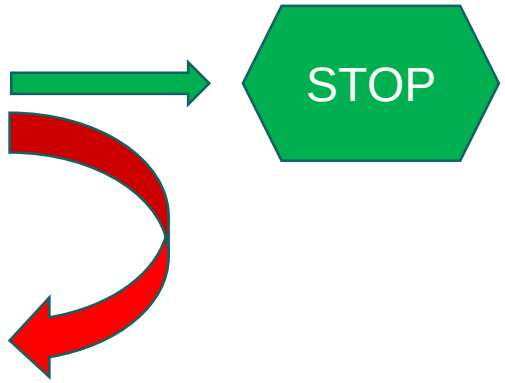
3- Additional studies

- If further investigation as required

8- Residues
9- 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

10 – Ecotoxicology

Summary information

- Pathogenicity/infectivity of MO: no need to test again if data on AS is still relevant!
- Toxicity of PPP: information already provided in the other sections
- Does this summary allow to conclude on toxicity?

STOP

Assessment of exposure

- Is exposure to the NTO absent based on information provided in F&B?

STOP

Toxicity studies

- Possibility of additional studies

Amendments of:

1. Data requirements for AS (Reg. 283/2013)
2. Data requirements for PPP (Reg. 284/2013)
3. Uniform principles (Reg. 546/2011)
4. Annex II to Regulation (EC) No 1107/2009

New:

5. EC Communication for AS
6. EC Communication for PPP

Approach for micro-organisms

Evaluation principles

- How the risk assessors should evaluate the data provided by the applicant (AS and PPP)?
- No need to list all the evaluation principles for each data requirement (it goes without saying that all the data requirements need assessment)
- List only data requirements were clarity is needed

Approach for micro-organisms

Decision-making principles

- All decision - making principles need to be listed!
- Decision-making principles:
  - risk-based (*i.e.* need exposure data and PPP use): they go in Reg. 546/2011 (Uniform Principles)
  - hazard-based (*i.e.* properties of the AS not linked to exposure): they go in Annex II to Reg. 1107/2009

Approach for micro-organisms

Some examples of the decision-making principles

- As indicated in the Annex II to Reg. 1107/2009, no approval of the AS shall be granted if the micro-organism:
  - is pathogenic to humans
  - is a bacterium with a known, functional and transferrable gene coding for resistance to medically important antimicrobials
- As indicated in the Reg. 546/2011 (Uniform Principles), no authorisation of the PPP shall be granted if:
  - the MO is infective for humans under the recommended conditions of use
  - there are not sufficient treatment options against the MO

Amendments of:

1. Data requirements for AS (Reg. 283/2013)
2. Data requirements for PPP (Reg. 284/2013)
3. Uniform principles (Reg. 546/2011)
4. Annex II to Regulation (EC) No 1107/2009

New:

5. EC Communication for AS
6. EC Communication for PPP

EC Communications

Aim and functioning

- Two different documents, one referring to the data requirements on microbial AS (Reg. 283/2013), and one to the data requirements on microbial PPP (Reg. 284/2013)
- Meant to indicate test methods and guidance documents to follow in order to fulfill the data requirements (but they are not legally binding)
- Only internationally-validated methods (e.g. OECD, EPA)
- In some cases (e.g. for testing pathogenicity of micro-organisms on bees) the test methods indicated need adaptation (e.g. extension of observational period), due to unavailability of validated methods

Thank you for your attention !

For further information:

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

Disclaimer

All views expressed are purely personal and should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information provided.

European Commission