Risk assessment of microorganisms – new data requirements

SANTE E4

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Farm to Fork and Sustainable use of pesticides

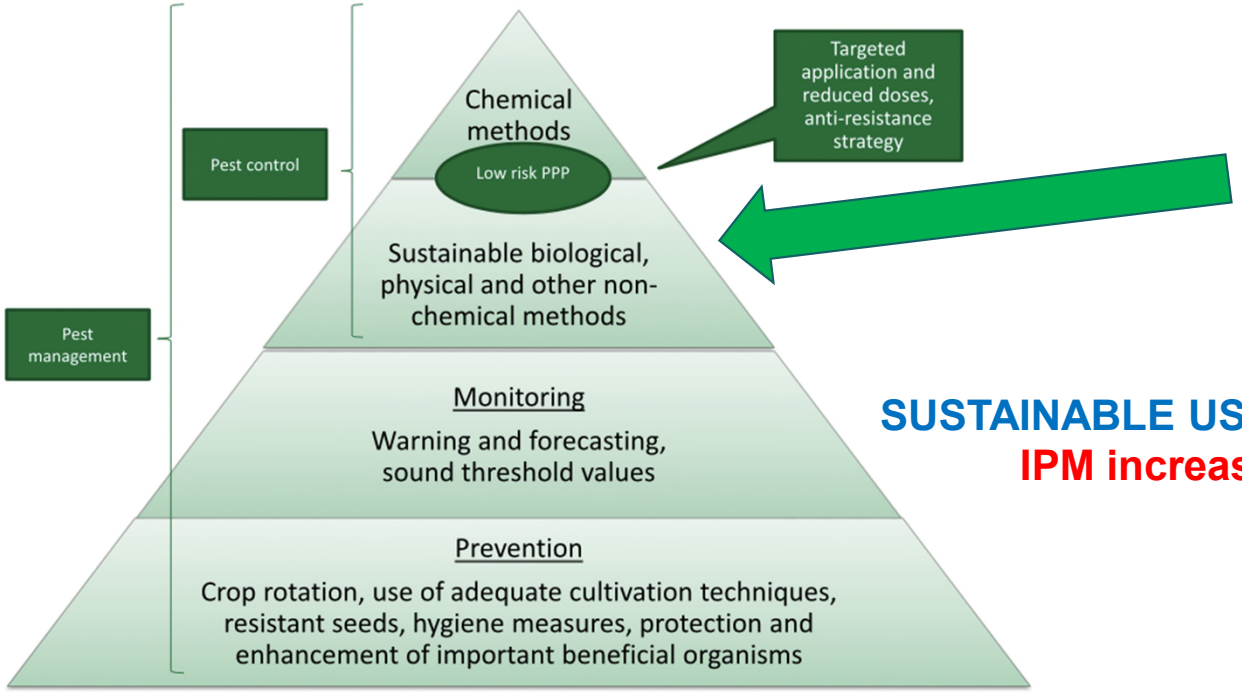
From Farm to Fork:
Our food, our health, our planet, our future

The European Green Deal

The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ **reduce by 50%** the use and risk of chemical pesticides by 2030.
- ✓ **reduce by 50%** the use of more hazardous pesticides by 2030.

Organic farming is an environmentally-friendly practice that needs to be further developed. The Commission will boost the development of EU organic farming area with the aim to achieve **25% of total farmland under organic farming by 2030**.



SUSTAINABLE USE OF PESTICIDES –
IPM increasingly central

European Commission

New Regulations on micro-organisms:

- Commission Regulation (EU) 2022/1439, amending Regulation (EU) No 283/2013 (data requirements active substances)
- Commission Regulation (EU) 2022/1440, amending Regulation (EU) No 284/2013 (data requirements plant protection products)

New Regulations applicable from 21 November 2022!

For active substance dossiers (**IUCLID**):

- Voluntary to the applicant until **21 May 2023** *(to specify choice in dossier, can not be changed later)*
- Compulsory to the applicant from **21 May 2023**

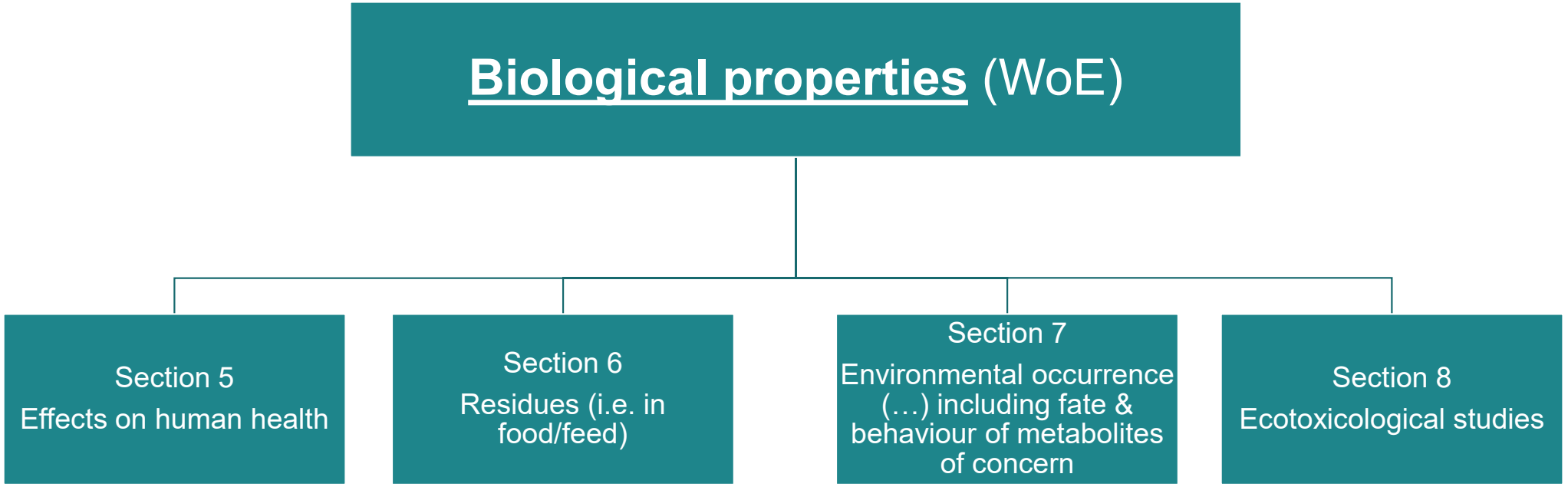
New Regulations on micro-organisms:

- Commission Regulation (EU) 2022/1438, amending Annex II to Regulation (EC) No 1107/2009 (specific criteria for the approval of AS that are MO)
- Commission Regulation(EU) 2022/1441, amending Regulation (EU) No 546/2011 (uniform principles for evaluation and authorisation of PPPs containing micro-organisms

New Regulations (decision making criteria) applicable to dossiers submitted from 21 November 2022!

Biological properties (Reg 283/2013)

- Central role in data requirements



European Commission

Tiered-based and weight of evidence approach

Example on human pathogenicity (Section 5 Reg 283/2013)

1- Weight of evidence approach (WoE)

- Biological properties
- Medical data
- Others

2- Pathogenicity and infectivity studies (new data generation)

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

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

- If WoE and pathogenicity and infectivity studies require further investigation

Annex II (identity and methods of analysis)

3.4. Composition of the active substance, safener or synergist

3.4.3. Active substances that are micro-organisms **shall be deposited** at an internationally recognised culture collection and shall have an accession number. The species' name of the micro-organisms **shall be identified unequivocally, based on the latest scientific information**, …

3.4.4. For active substances that are micro-organisms, the specification shall define the **minimum and maximum content of the micro-organism**, …

3.5. Methods of analysis

3.5.4. For active substances that are micro-organisms, the methods of analysis … **shall have been validated** and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.5. For active substances that are micro-organisms, the methods of analysis of metabolites of concern and relevant impurities shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.';

Annex II (decision making)

3.6.6. AS that are MO **shall only be approved** if, …the strain of the micro-organism is **not pathogenic to humans.**

In addition:

(a) viruses shall only be approved if, …the isolate of the virus is not infective to humans;

(b) strains of bacteria shall only be approved if, … they **do not have** any known, functional and **transferable gene coding for resistance to relevant antimicrobial agents**…

5.2. **Micro-organisms (low risk criteria)**

5.2.1. An active substance that is a micro-organism other than a virus may be considered a low-risk active substance unless its susceptibility to at least two classes of antimicrobial agents has not been demonstrated.

5.2.2. An active substance that is a virus may be considered a low-risk active substance unless it is:

(a) a baculovirus with demonstrated adverse effects on non-target insects; or

(b) a non-virulent variant of a plant pathogen with demonstrated adverse effects on non-target plants.'

Main comments from stakeholders consultation

Improvements from «old» Regulations:

- ✓ **increased clarity**
- ✓ **clear difference to chemicals**
- ✓ **solid grounds on biology and ecology**
- ✓ **weight of evidence can replace many animal studies**

Main comments from stakeholders consultation

Possible pitfalls:

- **interpretation issues: weight of evidence, flexibility VS legal certainty**
- **harmonisation and expertise among risk assessors**
- **not solving the lack of capacity among competent authorities**
- **discrepancy with similar regulatory framework (plant biostimulants) remains**

- ✓ **«explanatory notes» and other supporting documents**
- ✓ **Better Training for Safer Food**
- ✓ **Biopesticide WG (…and others)**
- ✓ **Implementation by Member States – make it happen!**

Road to 2030!

Micro-organisms (MO)

- **New Reg on MO** → EC Communications → Explanatory notes
- **OECD activities** → Test methods for MO → Consensus documents on MO
- **Other initiatives** (PF document, horizonal review)

MS capacity & peer review

- **New format DAR, EFSA Conclusion, Review/Renewal Report**
- **BTSF**
- **Relevant expertise MS (grants)**

European Commission

Make it happen!

European Commission