



European Union microbials data requirements

SANTE E4

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ABIM

25 October 2022

Farm to Fork and Sustainable use of pesticides

From Farm to Fork:

Our food, our health, our planet, our future

The European Green Deal

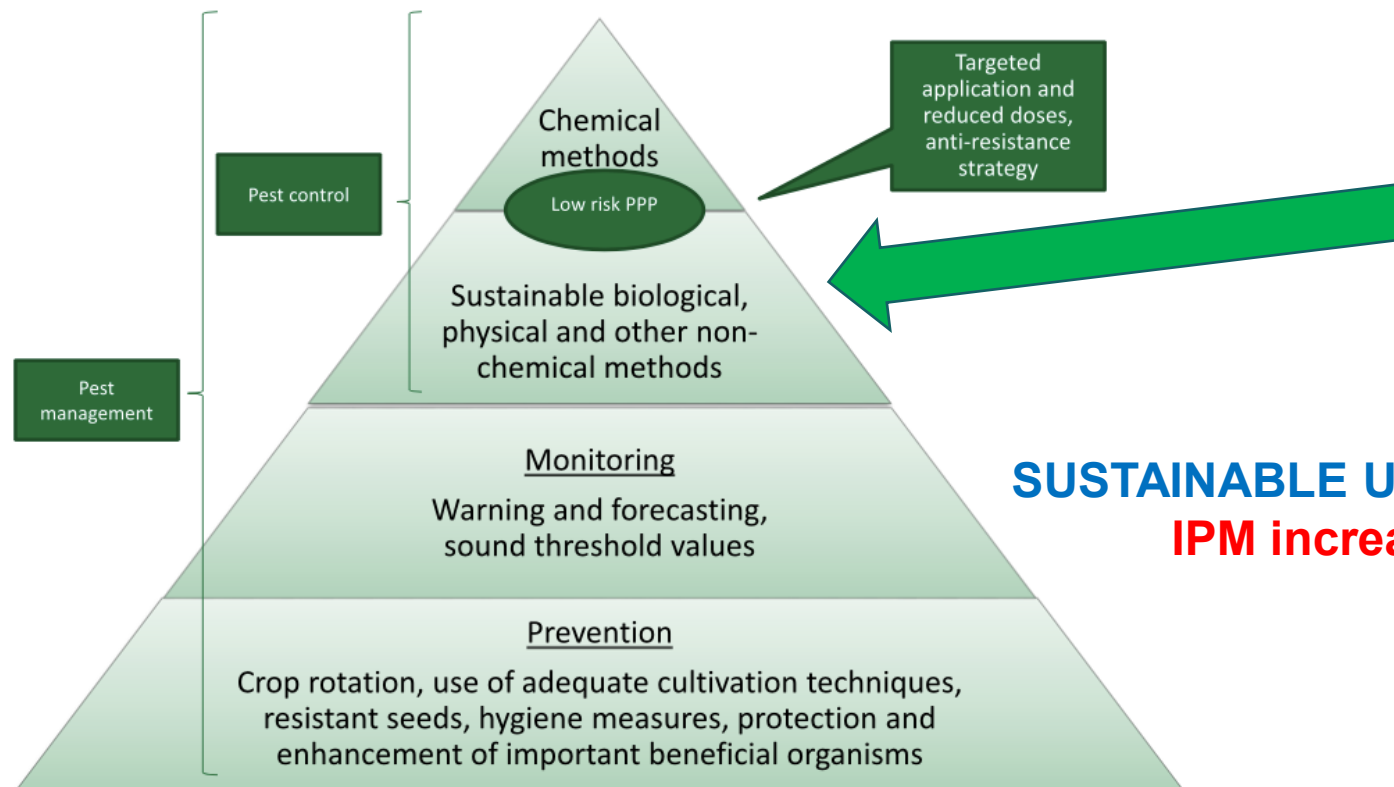


The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ 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**

Amendment of Regulations on micro-organisms:

- ❑ Reg. 283/2013 (data requirements AS)
- ❑ Reg. 284/2013 (data requirements PPP)

New Regulations applicable from 21 November 2022!

For active substance, new data requirements to be used:

- choice of applicant between **21 Nov 2022** and **21 May 2023**
- compulsory after **21 May 2023**

For products it will depend on the data requirements used for the active substance

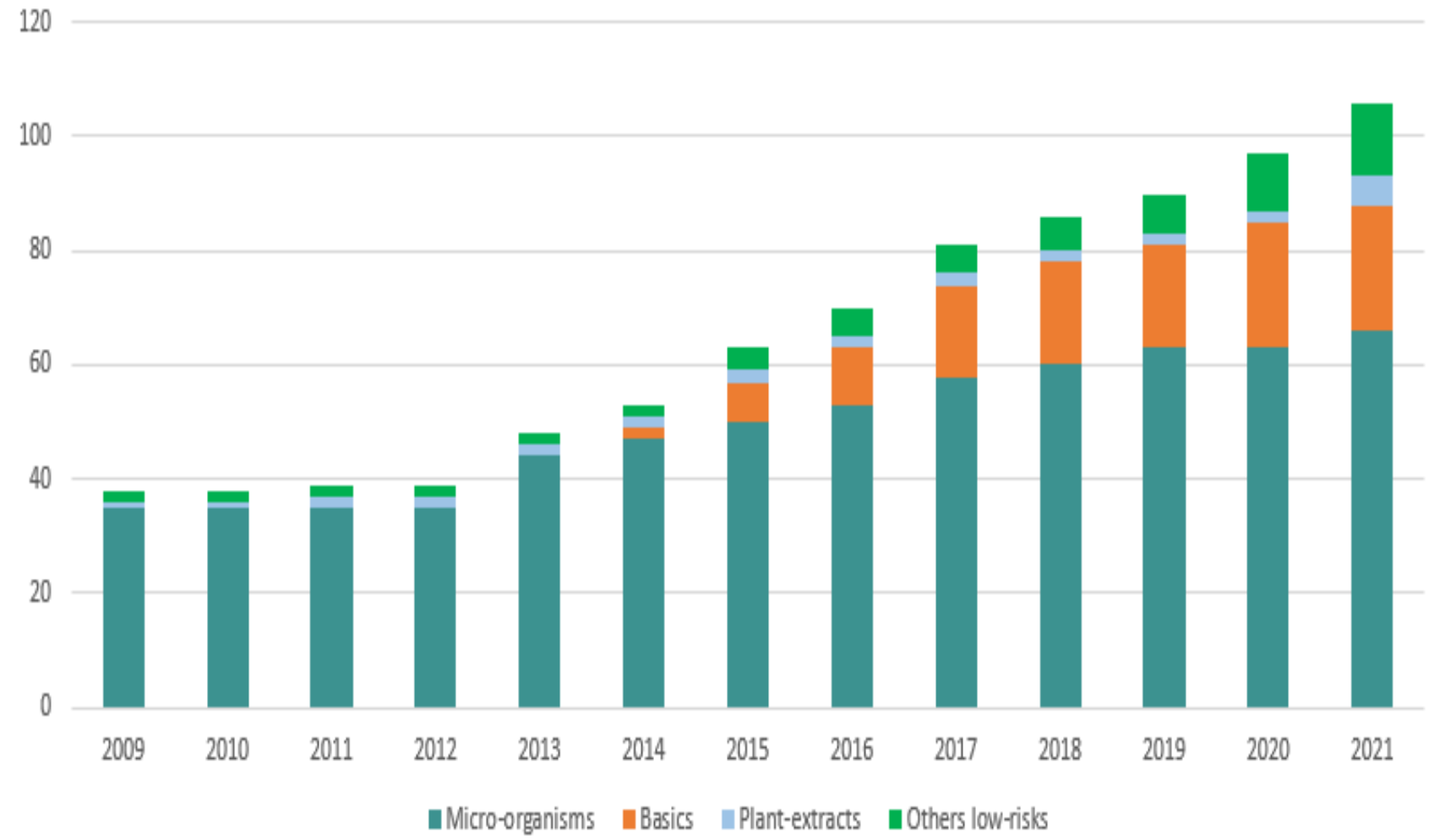
Amendment of Regulations on micro-organisms:

- Annex II Reg 1107/2009
- Reg. 546/2011 (Uniform Principles)

New Regulations applicable to dossiers submitted from 21 November 2022!

Revision of EU framework: why focusing on micro-organisms?

Low hazard active substances approved in EU



“Low risk” substances?
Organic farming?

Biological properties*

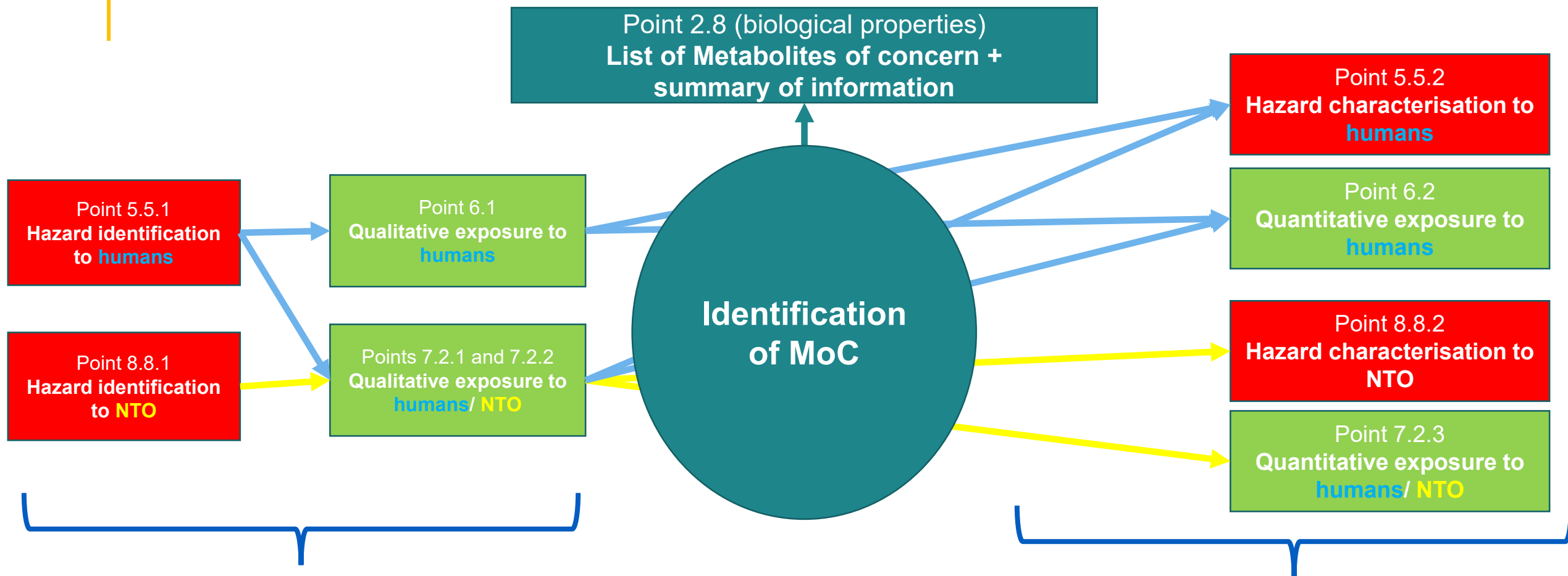
- **Central role** in data requirements (e.g. production of “metabolites of concern”)

Biological properties (WoE)



Tiered based approach

Example on metabolites of concern*



Called «metabolites» only (or of «potential concern» because we do not know yet if they are of concern or not)

Called «metabolites of concern» (we know they are of concern, and a risk assessment is needed)

Tiered-based and weight of evidence approach

Example on human pathogenicity*

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

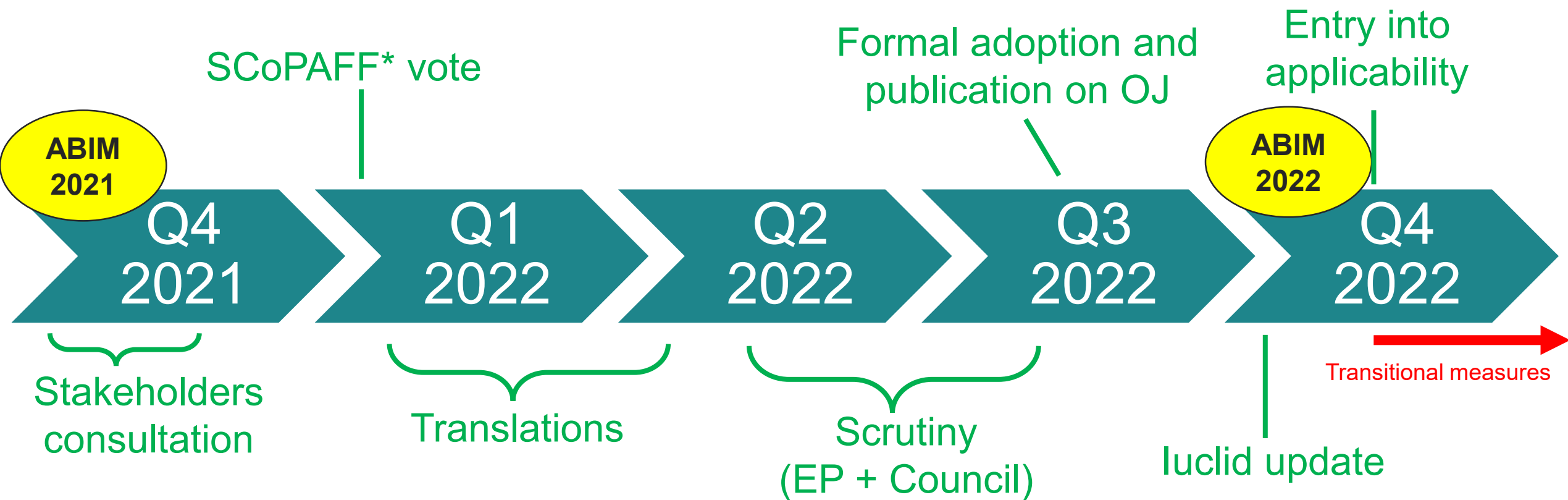


3- Specific pathogenicity and infectivity studies (new data generation)

- If WoE and pathogenicity and infectivity studies require further investigation



Progresses from ABIM 2021



Main comments from stakeholders consultation

Improvements from «old» Regulations:

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

Main comments from stakeholders consultation

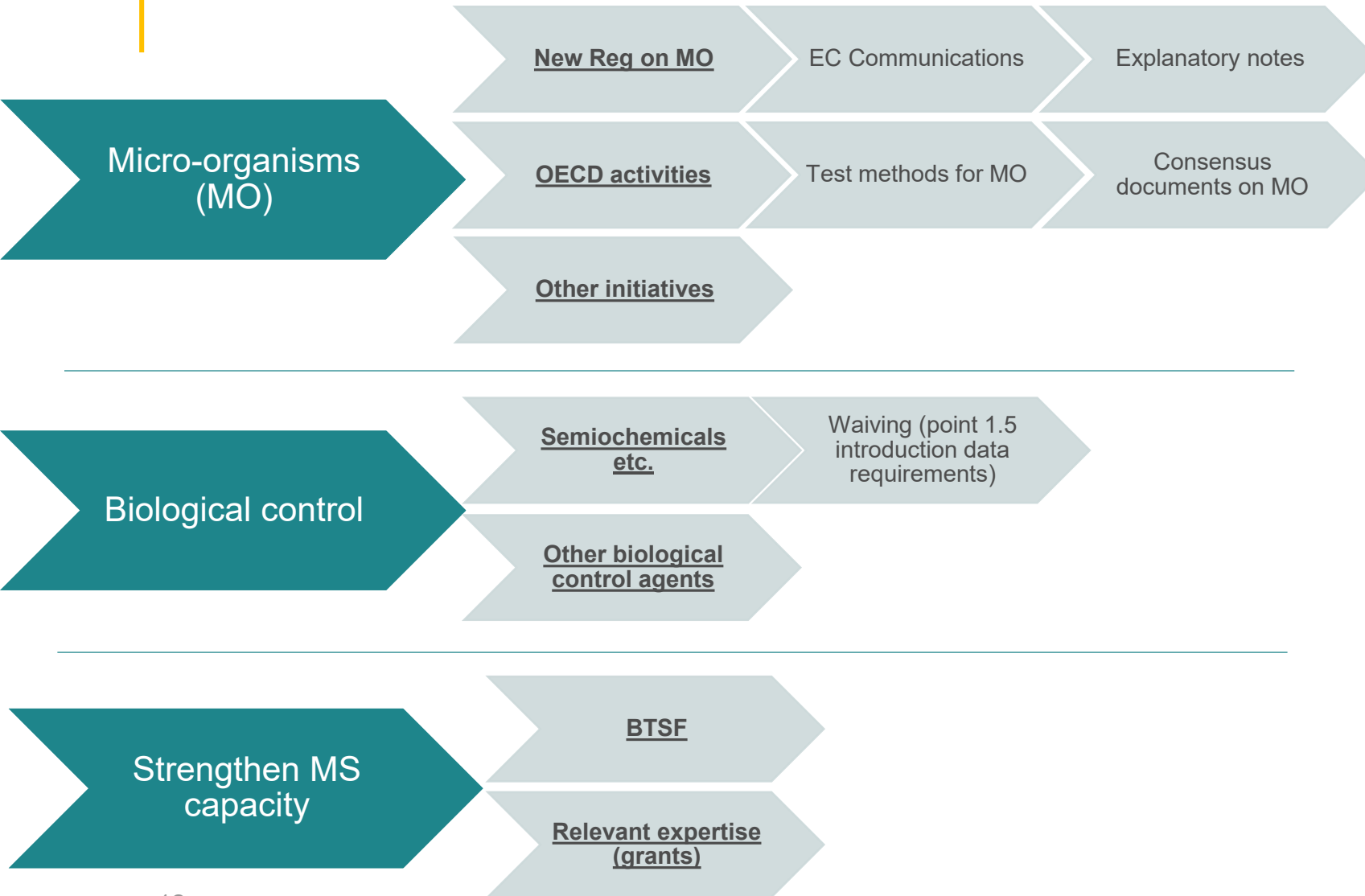
Possible pitfalls:

- **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)**
- ✓ **Some «pitfalls» out of scope!**

Road to 2030!



2030



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Thank you



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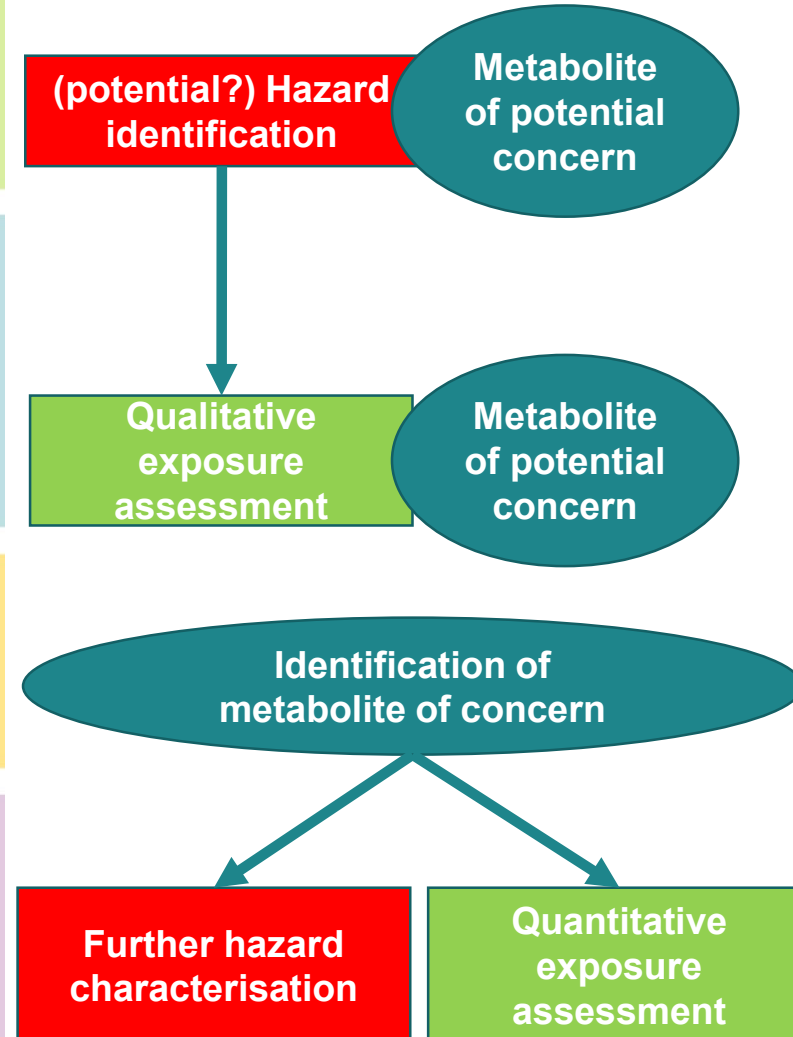
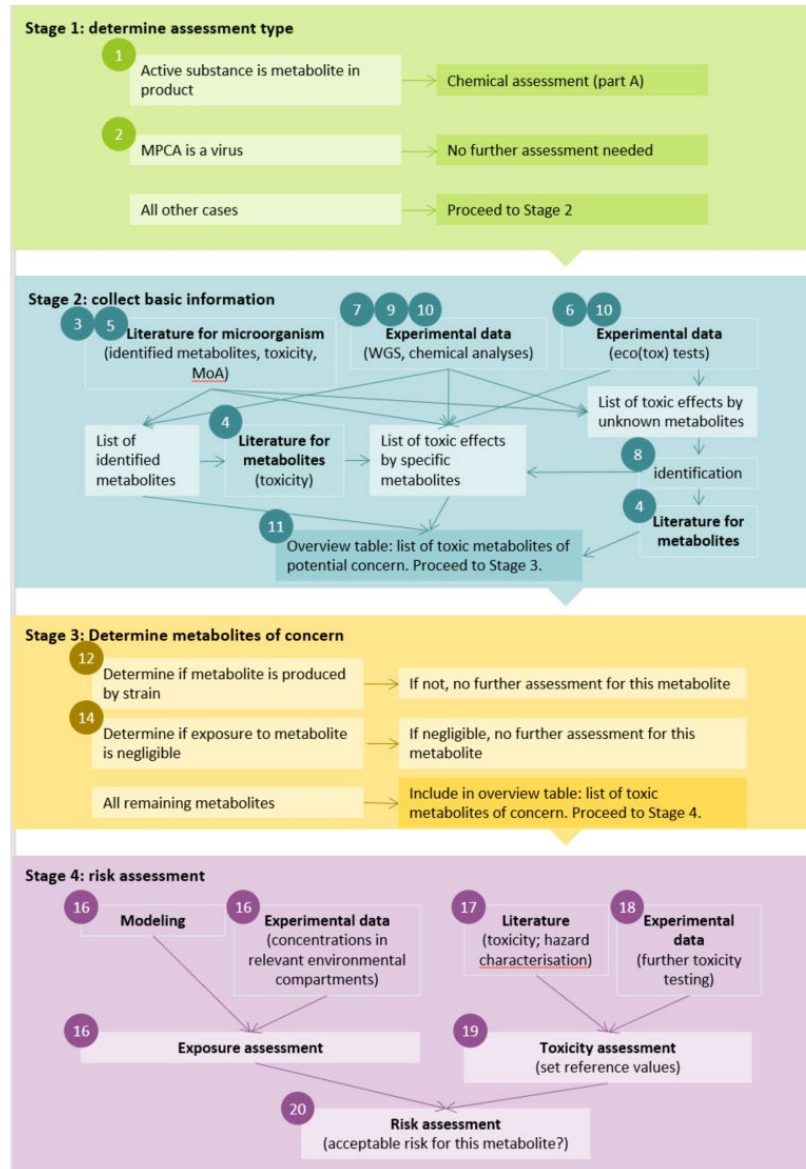
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Metabolites of concern

Guidance document on metabolites produced by micro-organisms*



Metabolites of concern

guidance on metabolites VS legal text

- **Guidance document:** sequence based on timings of data-provision (decision tree)



- **Legal text:** sequence based on dossier/DR structure

