Regulation of low risk active substances under Regulation 1107/2009
A need-to-know approach

EU Commission, SANTE E4

Eric LIEGEOIS

PBN Symposium 2022

17 November 2022

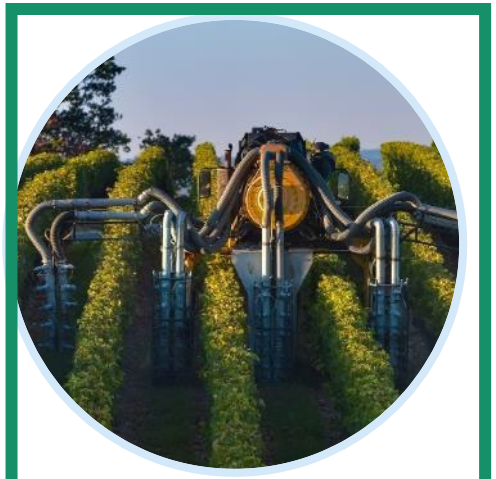
Content of the presentation

- Setting the scene: the political context
- Legal framework: marketing and use of plant protection products
- Need to adapt the existing legal framework for biological PPP
- Need-to-know principle applied to risk assessment of biologicals

The EU political context

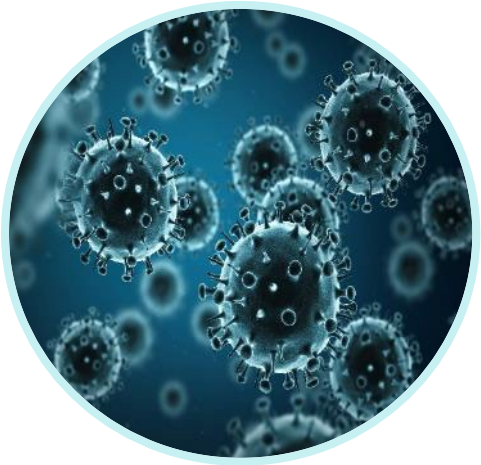
European Commission

The political context: Green Deal objectives



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 %

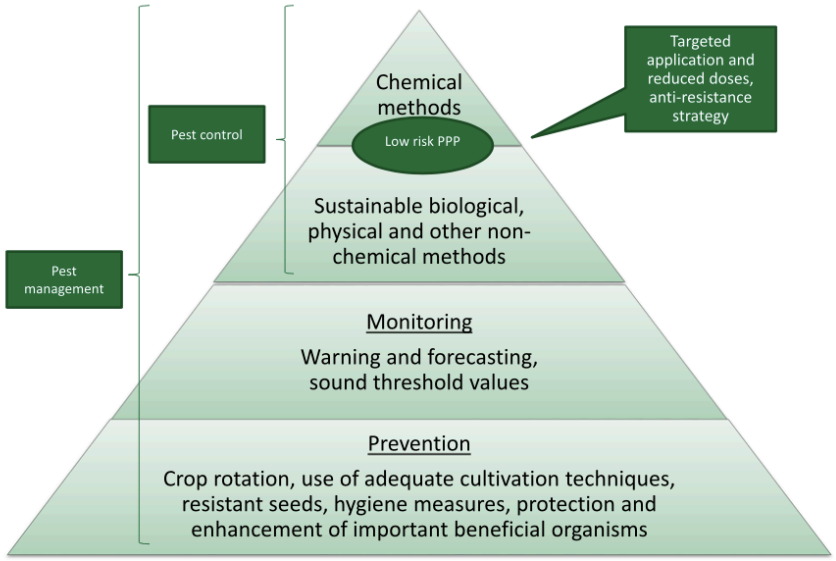


Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%

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

European Commission

The F2F strategy calls for more IPM and ….



….a more populated Farmers' toolbox with low-risk Solutions:

- **Micro-organisms,**
- **Pheromones,**
- **Peptides, antibodies,**
- **Beneficial insects/mites/nematods**

The F2F strategy calls for further implementation of Integrated Pest Management


N.R.


N.R.

Pest management

Pest control

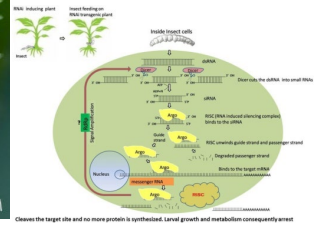
Chemical methods

Low risk PPP

Targeted application and reduced doses, anti-resistance strategy

Sustainable biological, physical and other non-chemical methods


N.R.



Monitoring

Warning and forecasting, sound threshold values

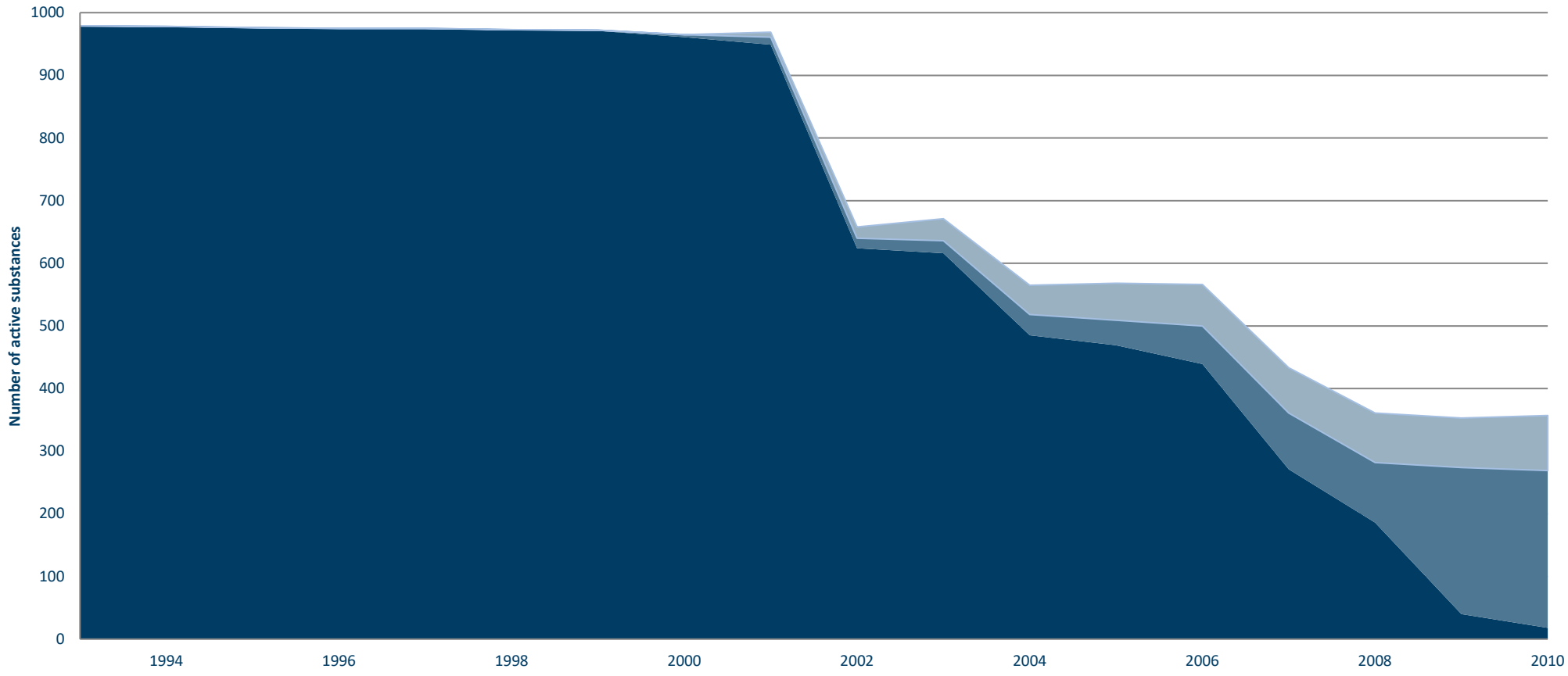
Prevention

Crop rotation, use of adequate cultivation techniques, resistant seeds, hygiene measures, protection and enhancement of important beneficial organisms

N.R.= Placing on the market is Not Regulated at EU

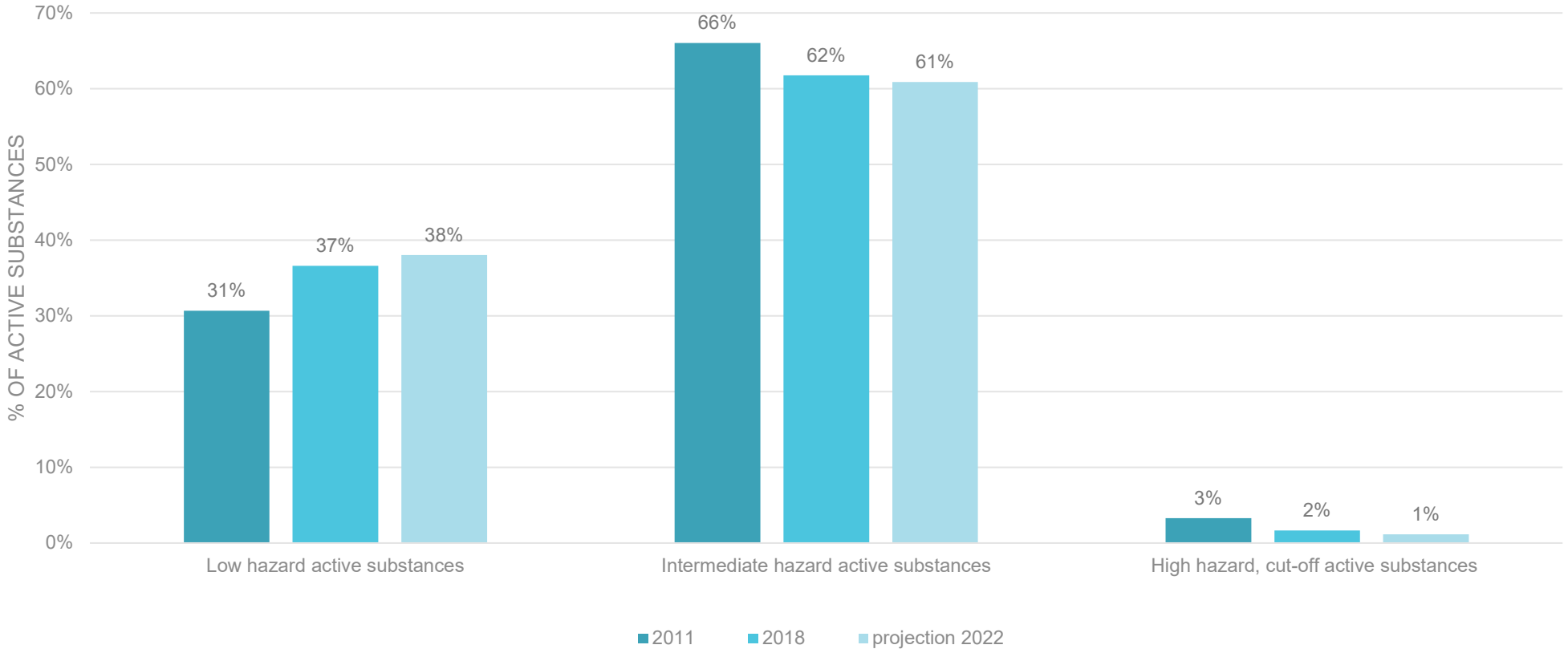
European Commission

How was the “portfolio” of active substances evolving in the EU between 1993 and 2010?



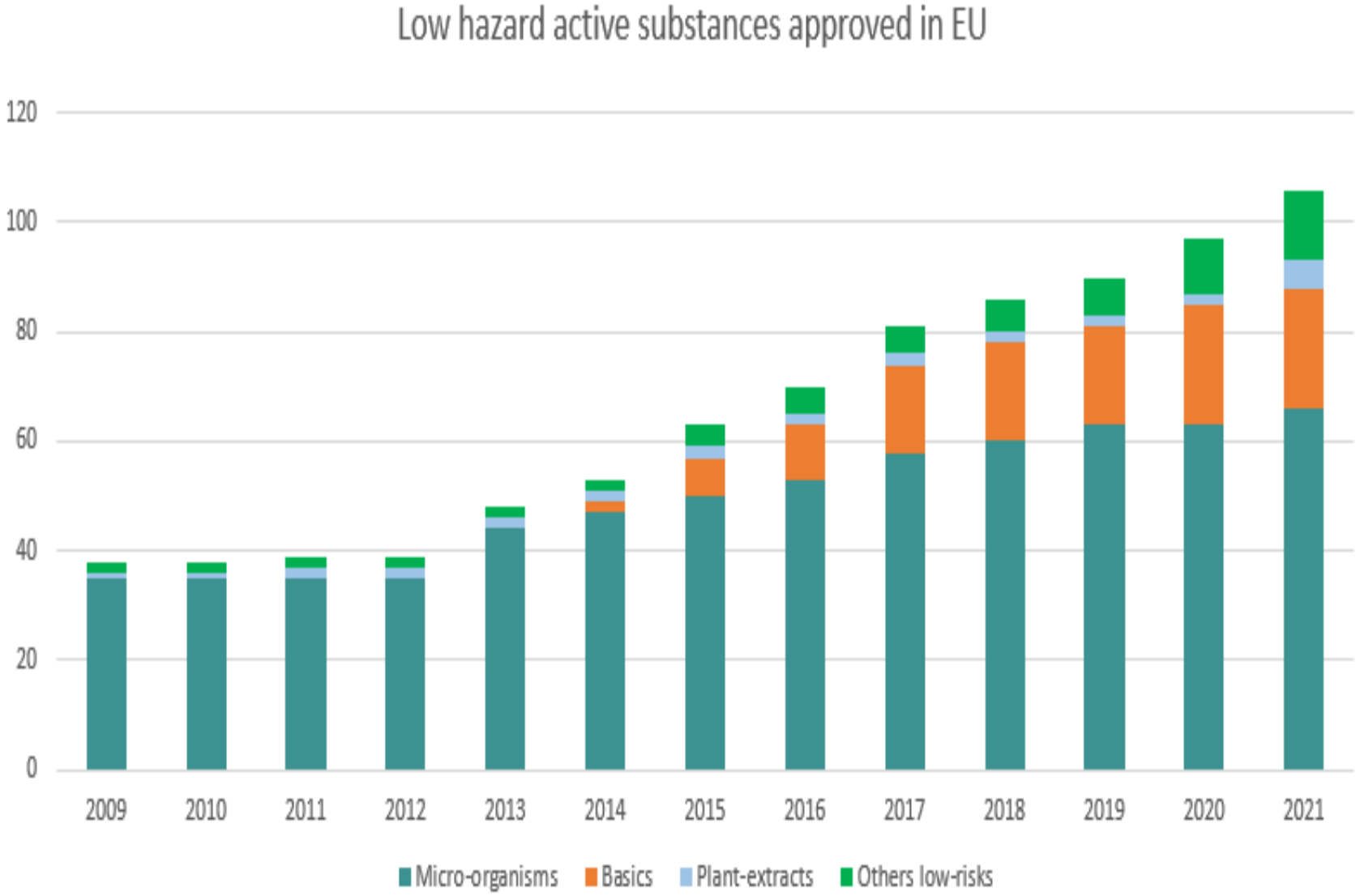
European Commission

Hazard Profiles of Active Substances



European Commission

What about the low-risk substances?



Today “Low risk” substances:

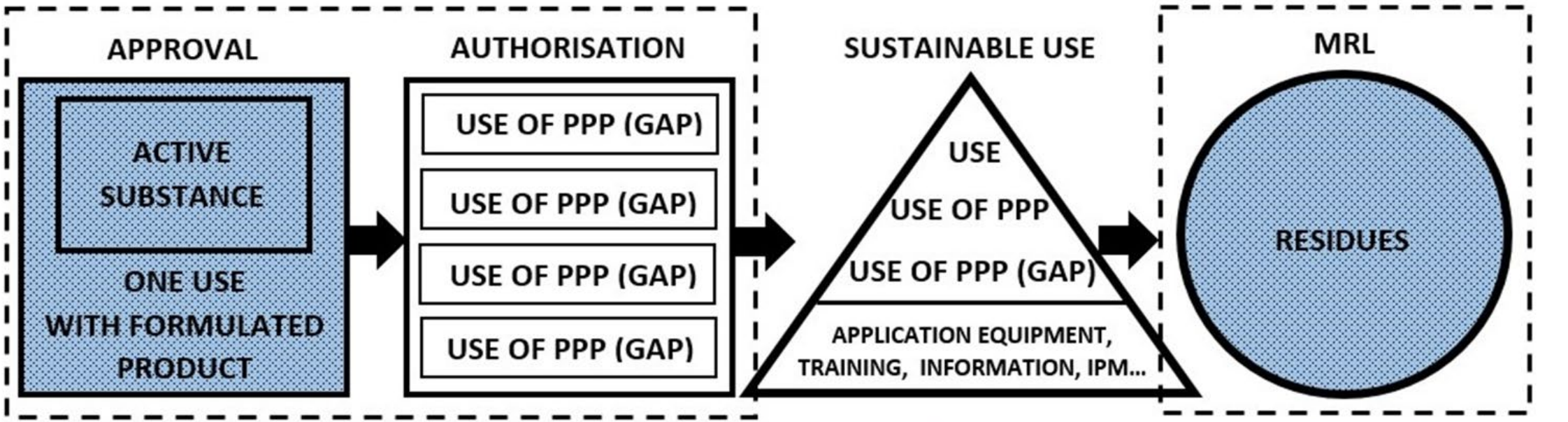
- Micro-organisms
- Pheromones
- Plant extracts

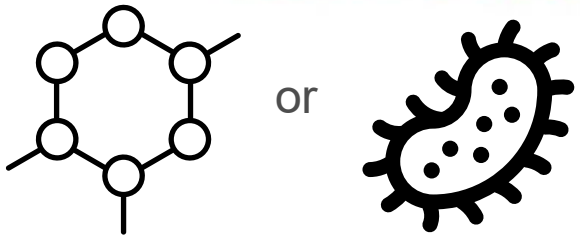
In the future:

- RNAi
- Peptides
- Antibodies

European Commission

Legal framework for plant protection products



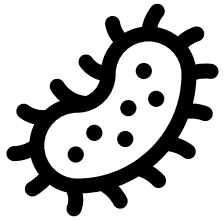


Efficient to protect HH and ENV, but better implementation (e.g. delays, transparency)

Update needed: proposal for Sustainable use Regulation (under discussion)

(Proposed definition of biological control)

Need to adapt the legal framework for biological PPP



Amendment of Regulations on micro-organisms:

- **Reg. 283/2013** (data requirements AS)
- **Reg. 284/2013** (data requirements PPP)
- **Annex II Reg 1107/2009**
- **Reg. 546/2011** (Uniform Principles)

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**

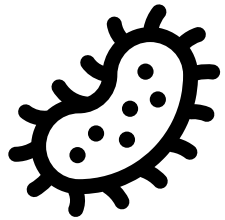
For products it will depend on the data requirements used for the active substance

14

European Commission

European Commission

Need-to-know approach in risk assessment
Biological properties*



- Central role in data requirements

Biological properties (WoE)

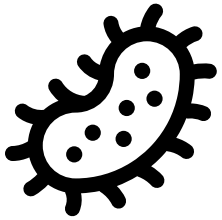
- Section 5 — Effects on human health
- Section 6 — Residues (i.e. in food/feed)
- Section 7 — Environmental occurrence (…) including fate & behaviour of metabolites of concern
- Section 8 — Ecotoxicological studies

European Commission

*Reg (EU) 283/2013 as amended by Reg (EU) 2022/1439

Tiered-based and weight of evidence approach

Example on human pathogenicity*



1- Weight of evidence approach (WoE)

- Biological properties
- Medical data
- Others

STOP

2- Pathogenicity and infectivity studies (new data generation)

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

STOP

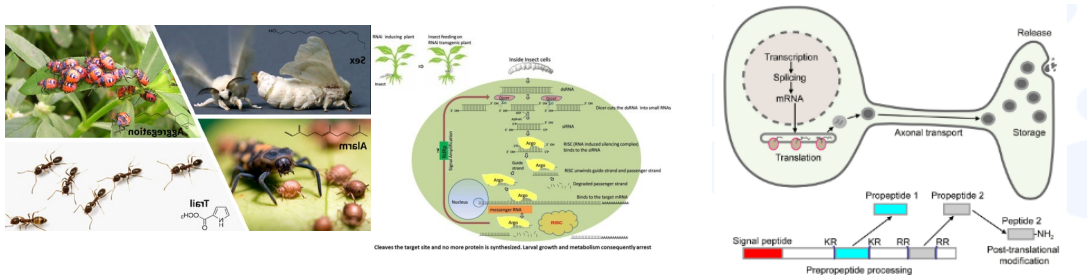
3- Specific pathogenicity and infectivity studies (new data generation)

- If WoE and pathogenicity and infectivity studies require further investigation

European Commission

*Section 5 of Reg (EU) 283/2013 as amended by Reg (EU) 2022/1439

Need-to-know approach for other candidate low-risk PPP in the 'pipeline'



- Data requirements (DR) & uniform principles
  - Part A dedicated to chemicals applies also to pheromones/semiochemical, botanicals-plant extracts, peptides, antibodies, RNAi)
  - EU guidance on semiochemicals, botanicals
- DR include literature data (systematic review, EFSA GD)
- DR include monitoring data (environment), epidemiological and medical data
- Info in DR not required under certain conditions (point 1.5 Introduction)
  - because of the nature, the uses, or **not needed scientifically**
  - technically not possible to generate

European Commission

Need-to-know approach for other candidate low-risk PPP – scientific justifications

- Biological properties
- Natural or already occurring background/exposure levels
- Ecology, fate and behaviour in the environment
- Specific interaction with the host
- Sensitivity to environmental factors → low-persistency…

Need-to-know approach for other candidate low-risk PPP – questions to discuss in your dossiers

Opportunity to „ask NEED-TO-KNOW “ data only: for ex.

- ?Existing risk assessment for other uses than PPP (unlikely due to the specific host/pest interaction)?
- ?Toxicity/ecotoxicity package: make sense (stability of those ‚chemicals‘?)?
- ?Consumers’ exposure: unlikely or equivalent to already occurring exposure”?

Need-to-know approach for other candidate low-risk PPP – from theory to practice

"When science leads, regulators try to follow"

- Authorities need to see the 'real cases' !
- Discussion before submitting the dossier between the company and the authority (e.g. "pre-submission meeting")
- Guidances to risk assessment: some are already available (EU, OECD, WHO), some others need to be developed.
- Every contributions are welcome: research projects, same technology applied to other uses, academic data collection, multiple actors joint efforts
- No need at this stage to modify the legal framework !

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**

Biological control

- **Semiochemicals etc.** → Waiving (point 1.5 introduction data requirements)
- **Other biological control agents**

Strengthen MS capacity

- **Training - BTSF**
- **Relevant expertise (grants)**

2030

European Commission

Keep in touch

ec.europa.eu/

europa.eu/

@EU_Commission

@EuropeanCommission

European Commission

europeancommission

@EuropeanCommission

EUTube

EU Spotify

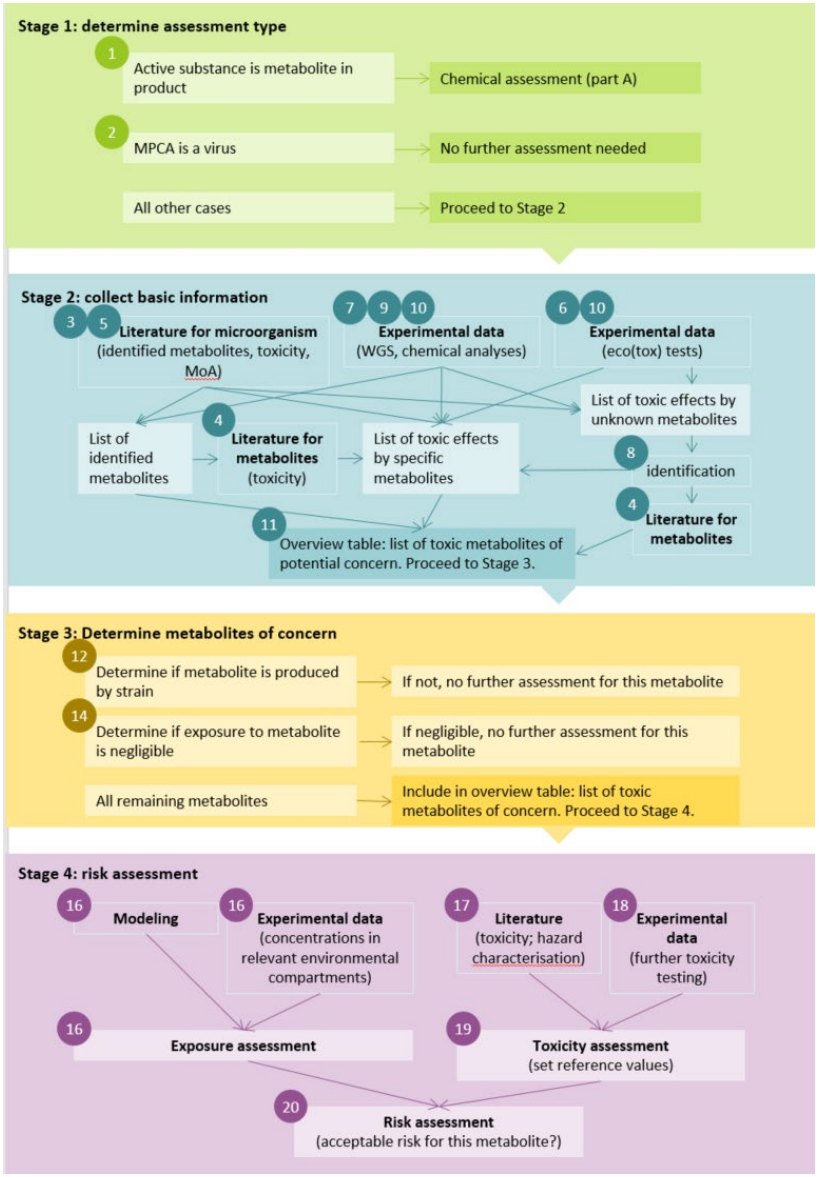
European Commission

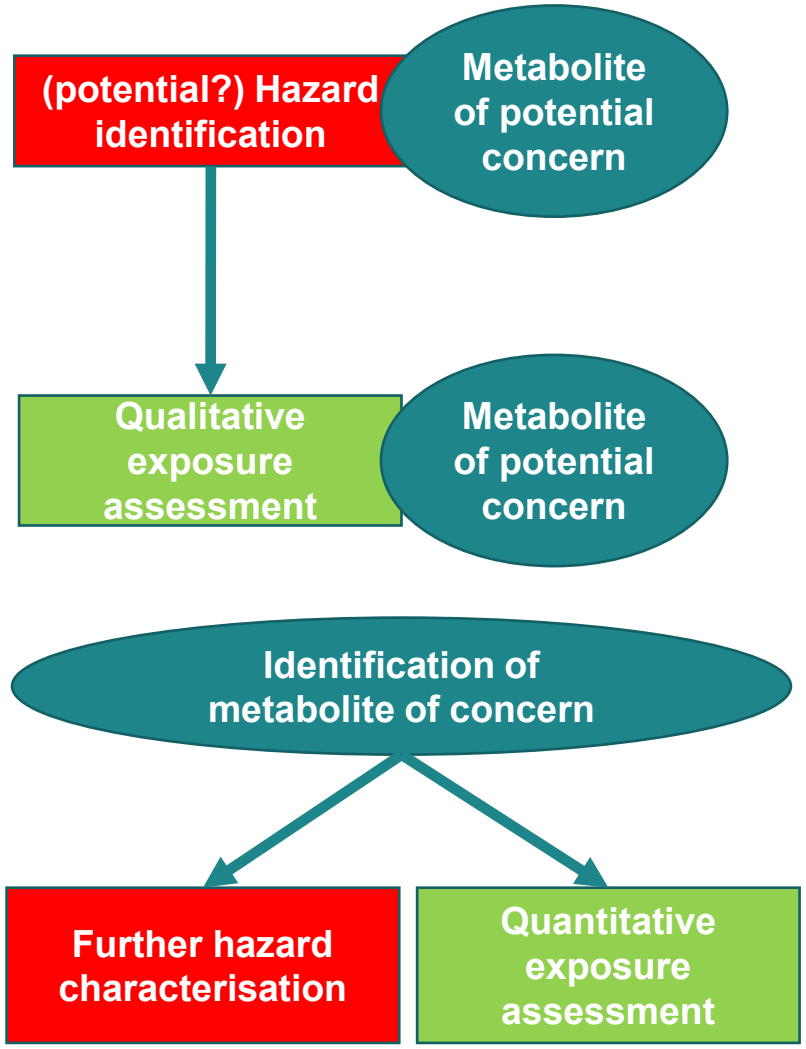
Thank you

European Commission

Metabolites of concern

Guidance document on metabolites produced by micro-organisms*





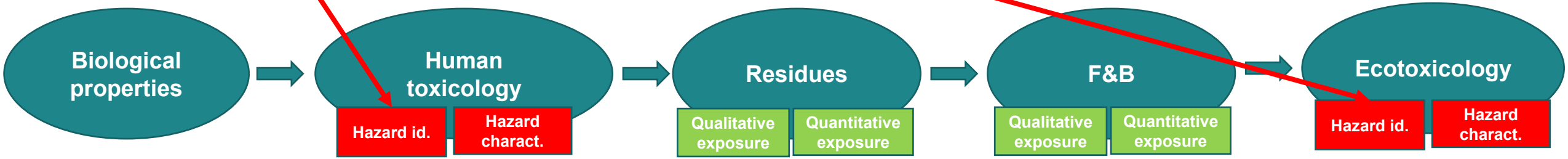
European Commission

* https://ec.europa.eu/food/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf

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



European Commission