



# AMR Requirements for micro-organisms used as active substances in plant protection products

SANTE E4 – Pesticides and Biocides

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# Why do we need biological plant protection products?



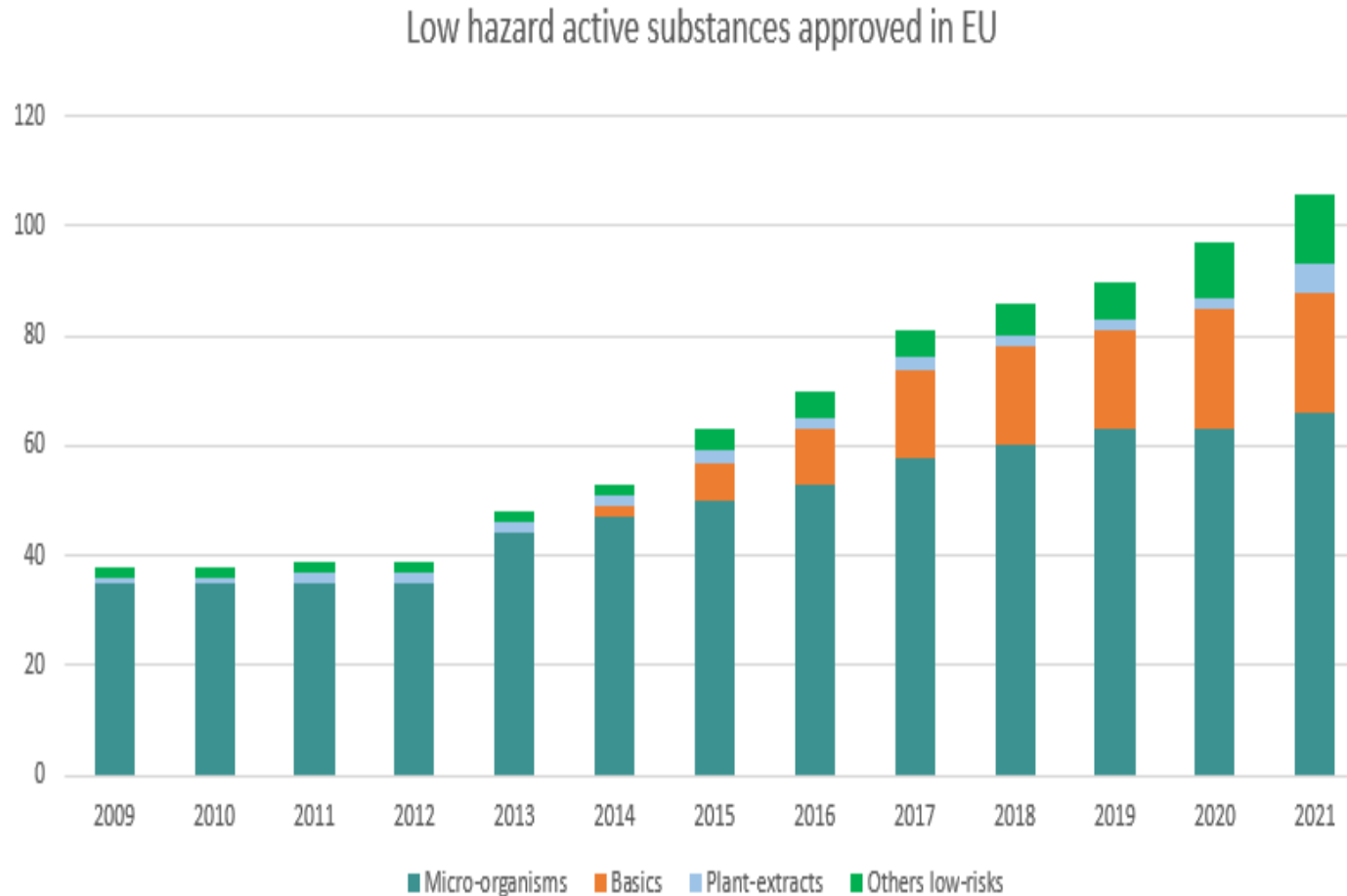
**The use of pesticides in agriculture** contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ **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.**

# Why focusing on micro-organisms?



How fostering access to market of micro-organisms to replace chemical pesticides???

# Amendment of four existing Regulations

## Data requirements and principles for evaluation and approval

- ❑ Stop mimicking chemical approach in risk assessment
  - ✓ Foster access to market of micro-organisms
  - ✓ Only needed data
- ❑ Embracing **evolution** of **scientific knowledge**
  - ✓ Risk assessment on micro-organisms
  - ✓ Emerging threats (e.g. **AMR!**)

## Farm to Fork



**Antimicrobial resistance** linked to the use of antimicrobials in animal and human health leads to an estimated 33,000 human deaths in the EU each year. The Commission will **reduce by 50% the sales of antimicrobials for farmed animals and in aquaculture by 2030.**

# Relevant amendments on AMR requirements

## Raise clarity!

### □ Clarity on definitions

- ✓ **AMR** (including “**Acquired**” and “**Intrinsic**” AMR)
- ✓ **Antimicrobial agent** (including “**relevant\***” antimicrobial agent)

### □ Clear separation between:

1. Availability of **treatment options**
2. Presence of relevant **AMR** genes and their possible **transfer**
3. **Production** of **antimicrobial agents** as secondary metabolites

# 1. Availability of treatment options

- ❑ Human pathogens cannot be approved!
- ❑ Opportunistic infections?
- ❑ Susceptibility to antimicrobial agents to have sufficient treatment options?? «Decision-making principle» OR «low-risk criterion»\*

## 2. Presence of relevant AMR genes and their possible transfer - *principles*

- ☐ On **bacteria** only
- ☐ Resistance to **relevant** antimicrobial agents?
  - ✓ WHO and veterinary list
- ☐ **known, functional** and **transferrable** gene encoding for it?
  - ✓ Intrinsic VS acquired
- ☐ Phenotypic and genotypic assessment (**guidance\***)
- ☐ «approval criterion»

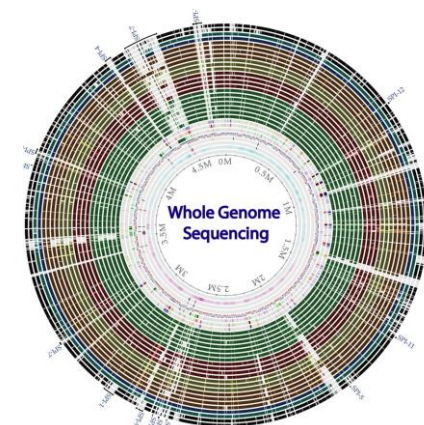


## 2. Presence of relevant AMR genes and their possible transfer – *guidance on AMR\**

### Stepwise approach

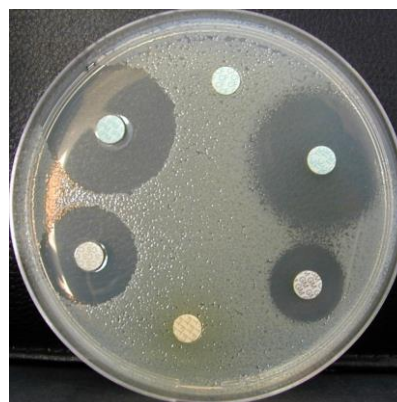
#### I. Whole Genome Sequencing (WGS)

- ✓ AMR gene identified?
- ✓ AMR gene present and transferable?



#### II. Phenotypic testing

- ✓ Susceptible or resistant?





# 3. Production of antimicrobials as secondary metabolites - *principles*

- ❑ Not for viruses

- ❑ Referred to antimicrobial agents which are:

  - ✓ “relevant\*”

  - ✓ produced during manufacturing (no “*in-situ*” production)

- ❑ Guidance\*\*

- ❑ «Decision-making principle»

# 3. Production of antimicrobials as secondary metabolites – *guidance on “metabolites of concern”*\*

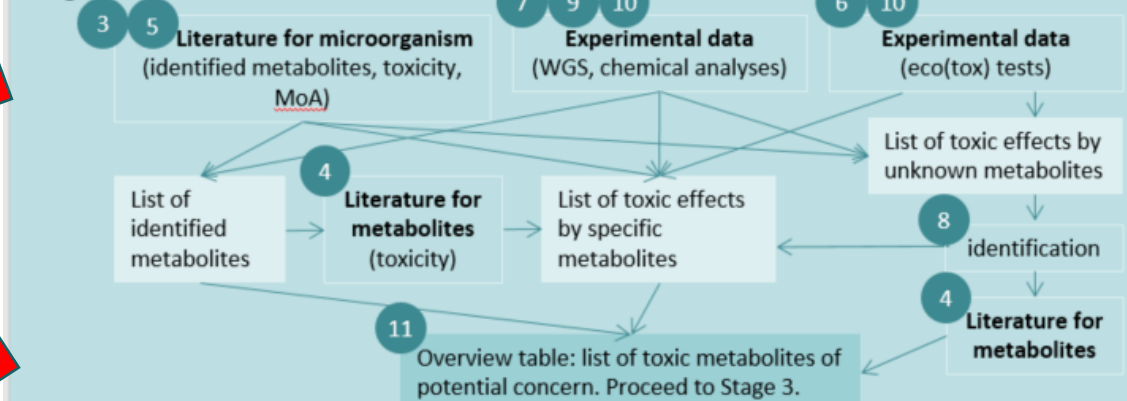
## Stage 1: determine assessment type



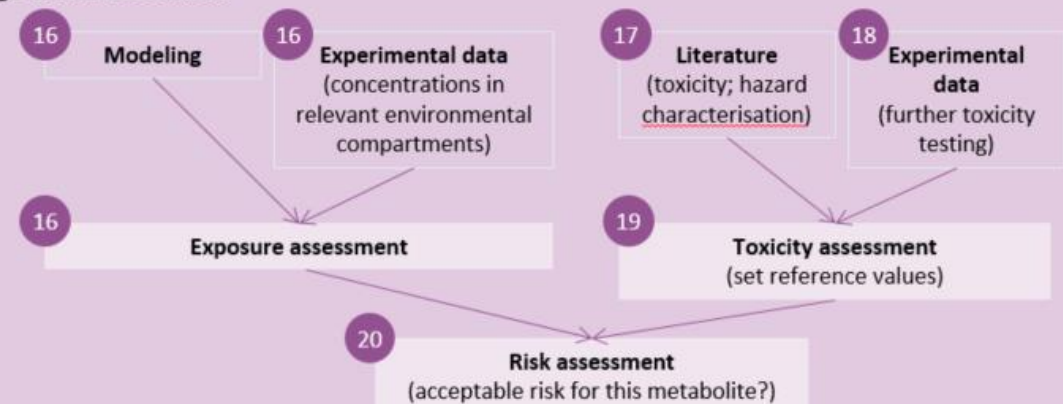
## Stage 3: Determine metabolites of concern



## Stage 2: collect basic information



## Stage 4: risk assessment



# Take-home messages

- ❑ Micro-organisms used in biological plant protection products shall comply with requirements on AMR
- ❑ The new regulatory framework increases clarity and relevance on AMR requirements

# Thank you



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