



# Biopesticides: Towards ambitious and fit-for-purpose EU policies

SANTE E4 – Pesticides and Biocides

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*CropLife Europe, 11 March 2021*

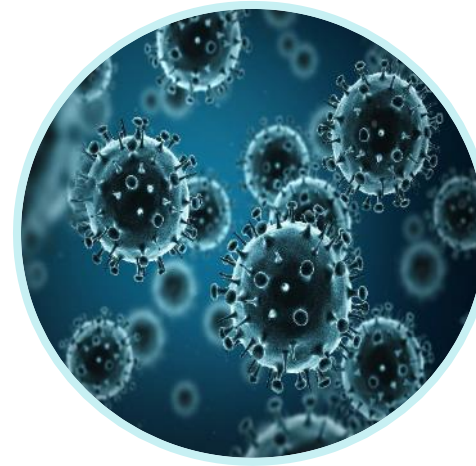
# 2030 Targets for sustainable food production



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 %

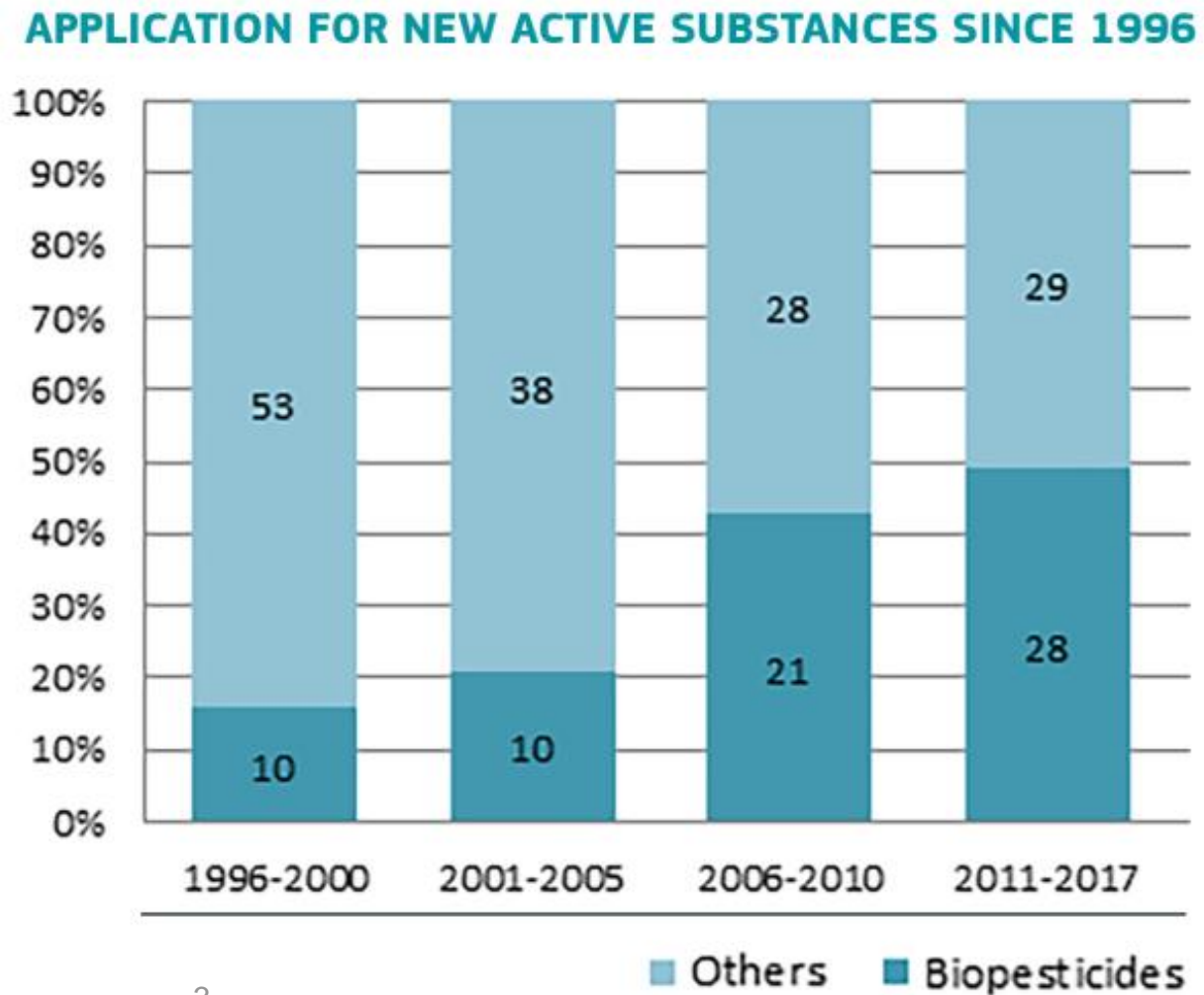


Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%



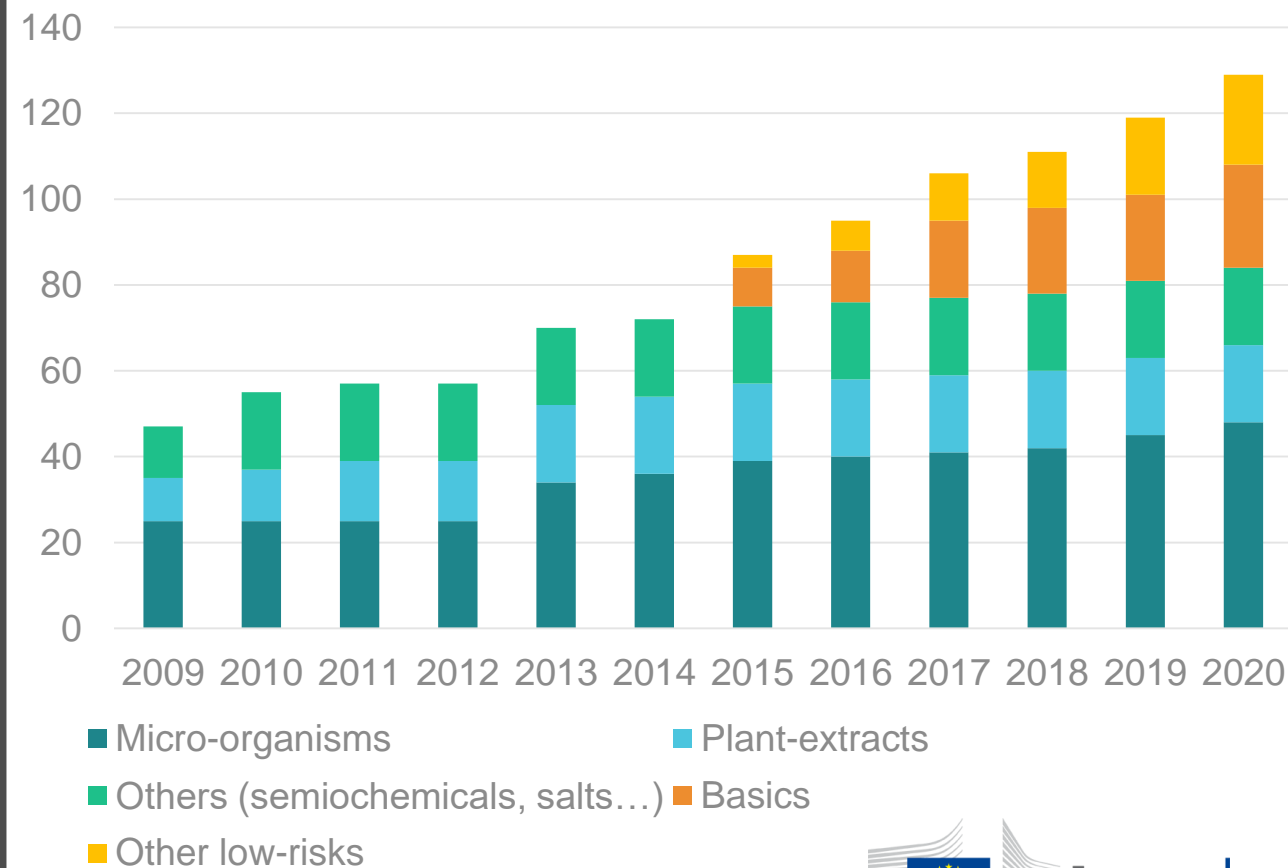
Achieve at least 25% of the EU's agricultural land under **organic farming** and a significant increase in **organic aquaculture**

# Increasing availability of biopesticides and microorganisms



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## Low hazard active substances approved in EU



# Initiatives for micro-organisms

## ❑ Revision of concerned Regulations:

- ✓ Reg. 283/2013 active substances, part B
- ✓ Reg. 284/2013 PPP, part B
- ✓ Reg. 546/2011 uniform principle, part B
- ✓ Annex II Reg. 1107/2009 (specific approval criteria for micro-organisms)

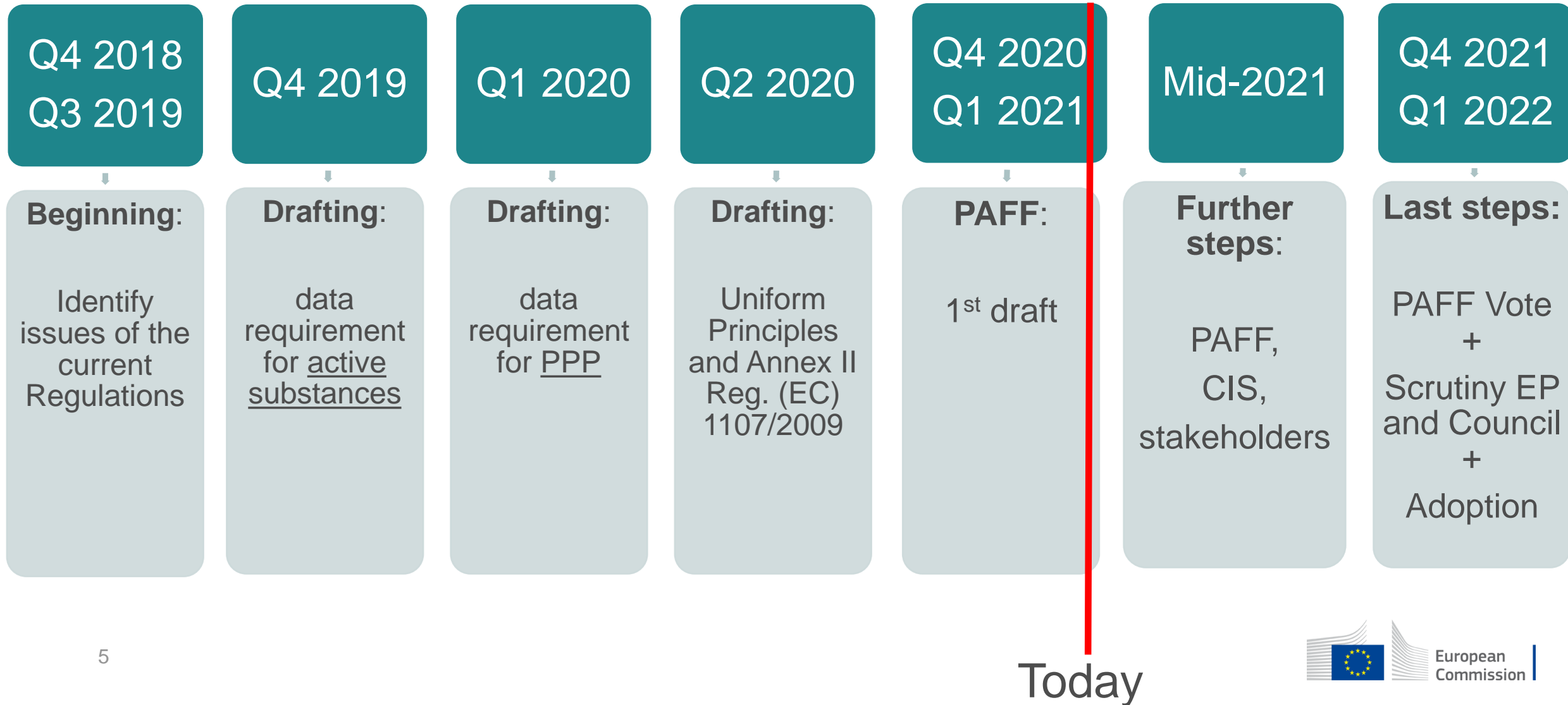
## ❑ Guidance documents:

- ✓ risk assessment of metabolites produced by micro-organisms
- ✓ approval and low-risk criteria linked to antimicrobial resistance

## ❑ Better Training for Safer Food

# Revision of concerned Regulations

## Milestones of activities of Biopesticide WG



# Revision of concerned Regulations

## Some technical contents (i)

- ❑ Reconsidering the relevance of acute pathogenicity studies on animals
  - ✓ Host-specificity range and reliability
  - ✓ Importance of pre-submission meetings (e.g. amendment of General Food Law)
  - ✓ Weight of evidence approach (e.g. biological properties, Qualified Presumption of Safety, scientific literature)
  
- ❑ Weight of evidence approach – possible applications
  - ✓ Human toxicology/pathogenicity studies
  - ✓ Ecotoxicology studies (e.g. exposure/pathogenicity?)
  - ✓ Metabolites of concern (identification/exclusion of metabolites of concern)

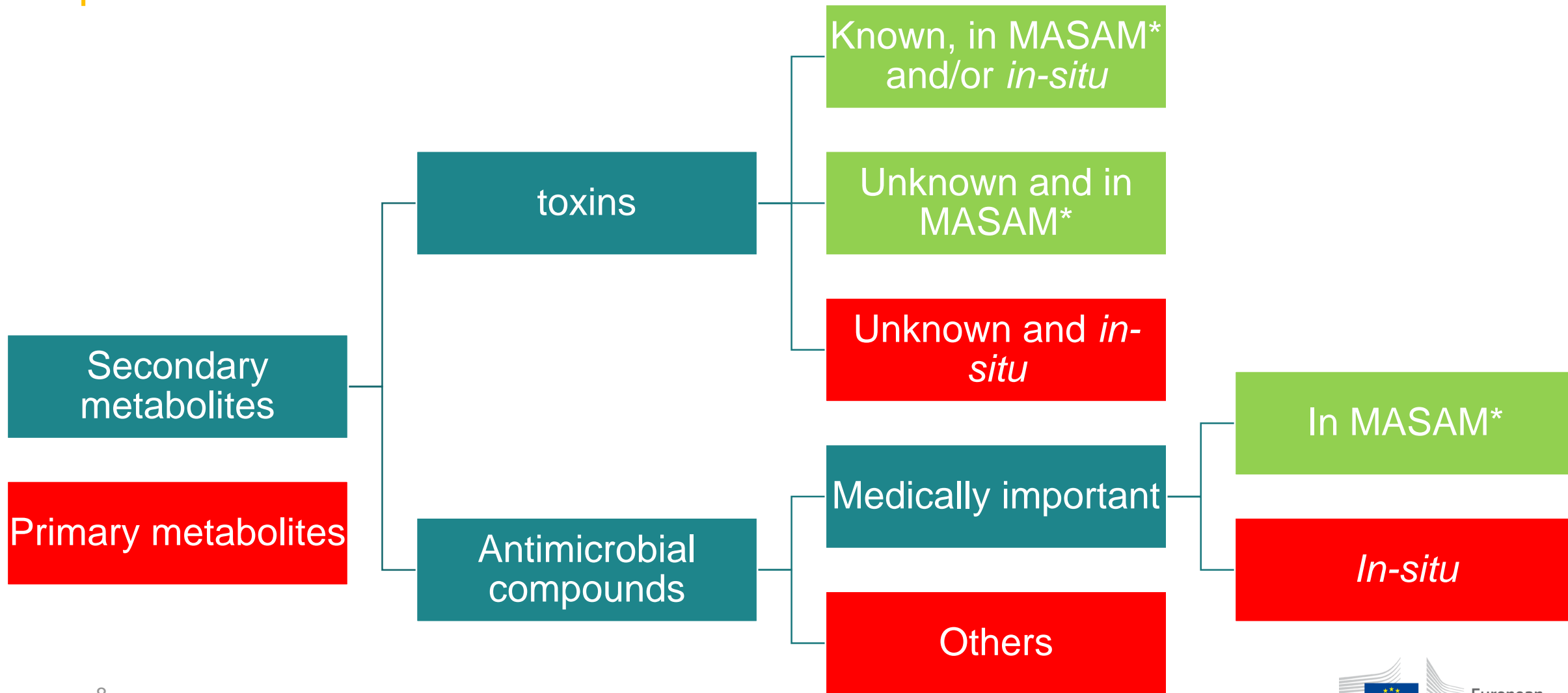
# Revision of concerned Regulations

## Some technical contents (ii)

- ❑ Pathogenicity/infectivity VS toxicity
  - ✓ Clear separation of the assessments:
    - microorganism: pathogenicity/infectivity
    - metabolites of concern and relevant chemical components of PPP: toxicity
  
- ❑ Metabolites of concern
  - ✓ Waiving opportunities offered by genomics
  - ✓ Developments on the guidance document

# Identification of metabolites of concern

(guidance document on the risk assessment of metabolites produced by MO)





# Identification of metabolites of concern

(application in the data requirements)

## Identification of metabolites of concern



# Guidance document on approval and low-risk criteria linked to antimicrobial resistance

- ❑ Some technical content:
  - ✓ Medically Important Antimicrobial only (i.e. WHO definition)
  - ✓ Two steps:
    1. WGS – screening known AMR genes
    2. Phenotypic approach – MIC
- ❑ Entry into force mid-2021

# Better Training for Safer Food

## Organisation and Implementation of Training Activities on the Risk Assessment of Microorganisms used as Pesticides or Biocides under the 'BTSF' Initiative

- ❑ Aimed outcome: increase specific expertise on risk assessment of microbial active substances and PPP
- ❑ Aimed benefit: accelerate access to market of microbial active substances and PPP
- ❑ Subjects: 210 risk assessors (MS, EFTA/EEA,, candidate and potential-candidate countries), Commission and Agencies' staff (EFSA, ECHA).
- ❑ Process:
  - ✓ Nov 2019: publication of call for tender published
  - ✓ Q2 2020: award of contract and kick-off meeting
  - ✓ <sup>11</sup> Training activities for 2021-2022 (+2 more years)

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# Thank you



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