New EU initiatives in regulating microbial plant protection products

SANTE E4

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ABIM, 20 October 2020

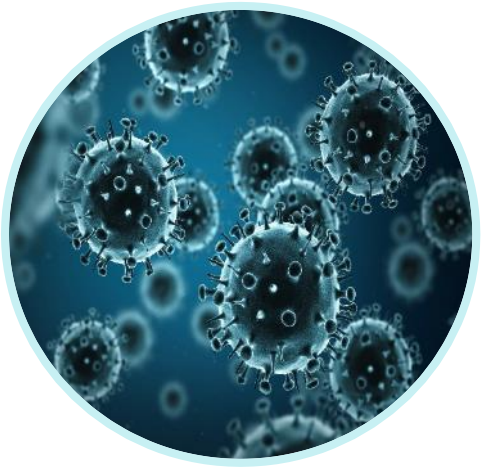
The European Green Deal

European Commission

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 %

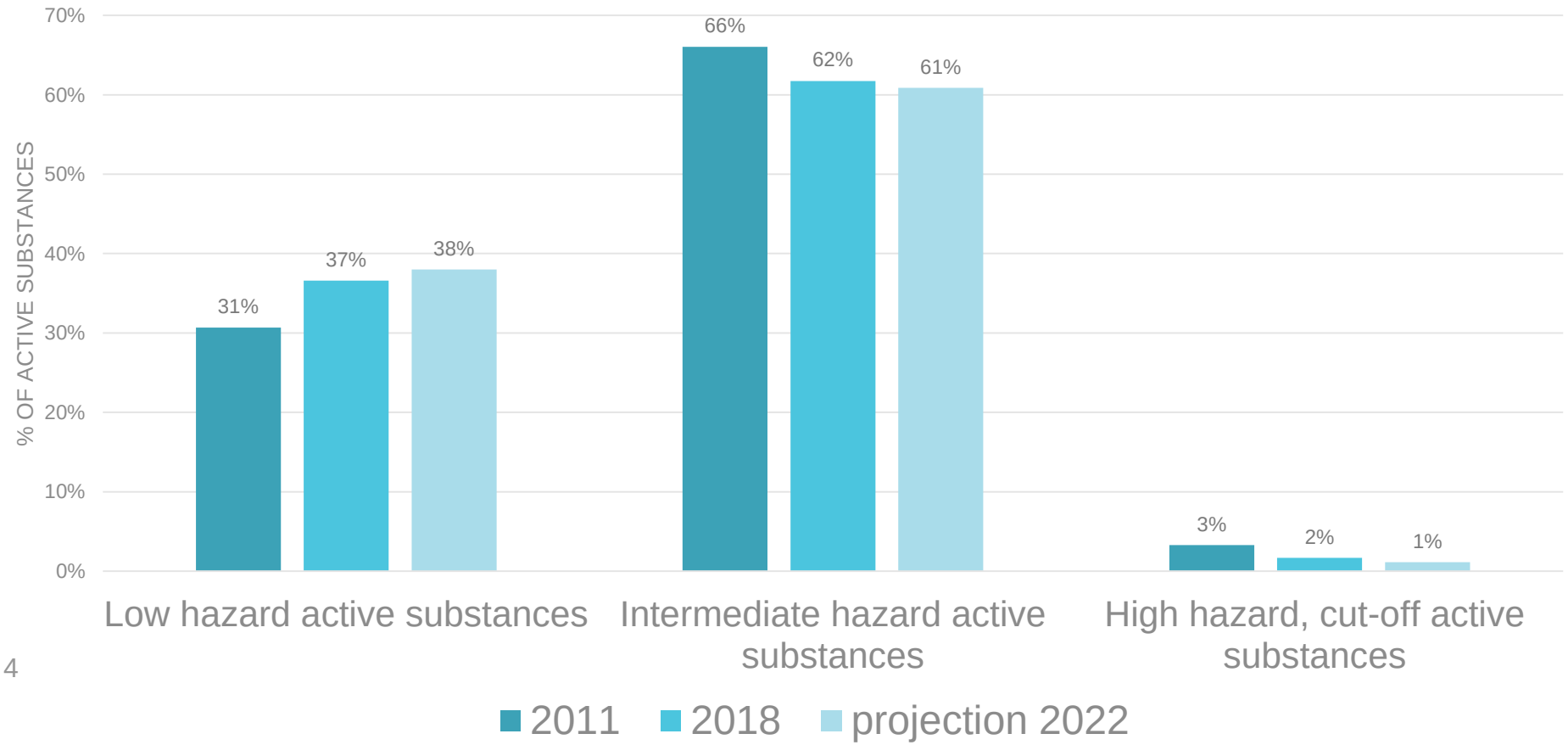


Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%

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

REFIT - Reducing use of hazardous substances

- Evaluation found that PPP Regulation is effective in protecting human health and the environment due to the stringency of the approval criteria



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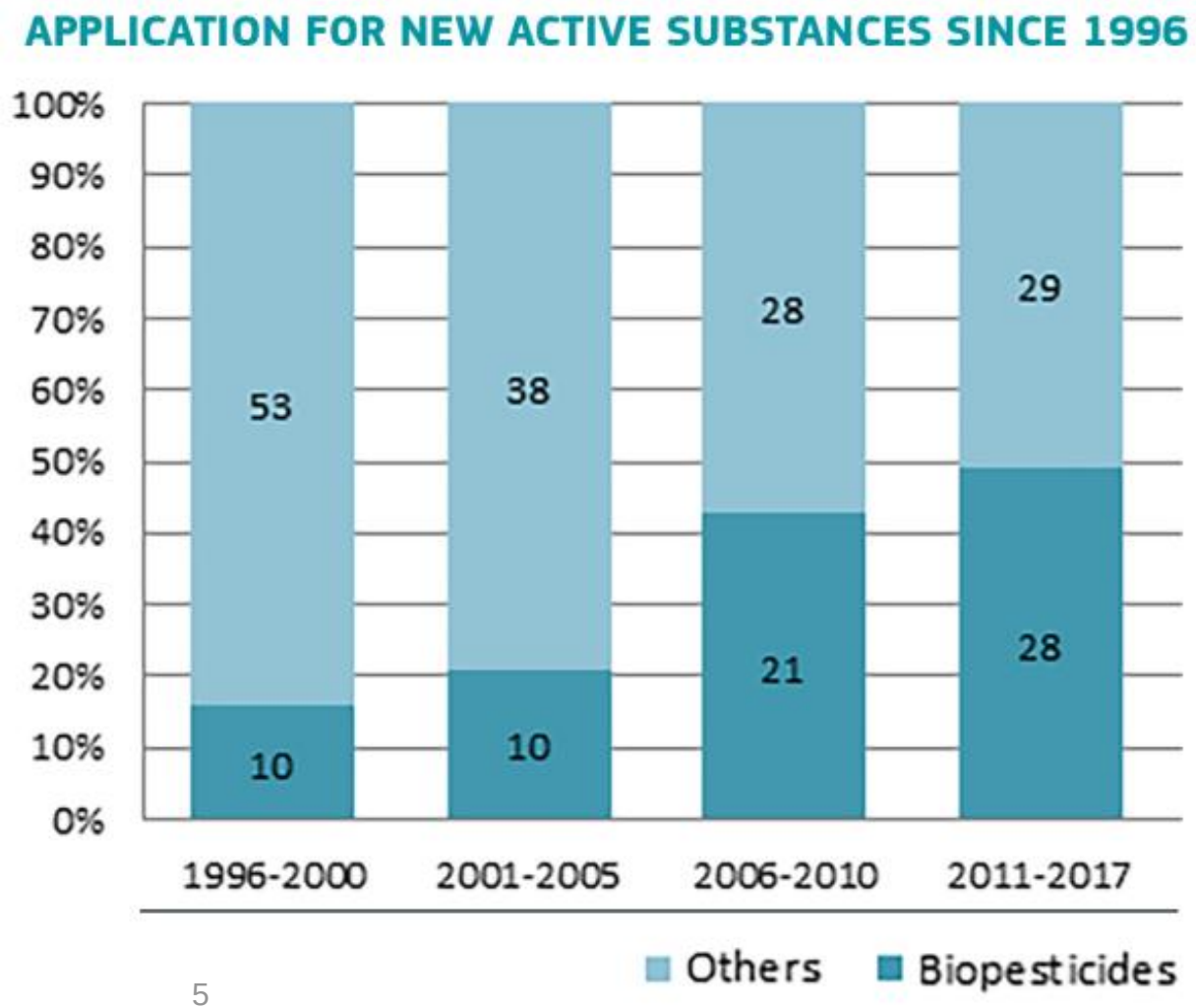
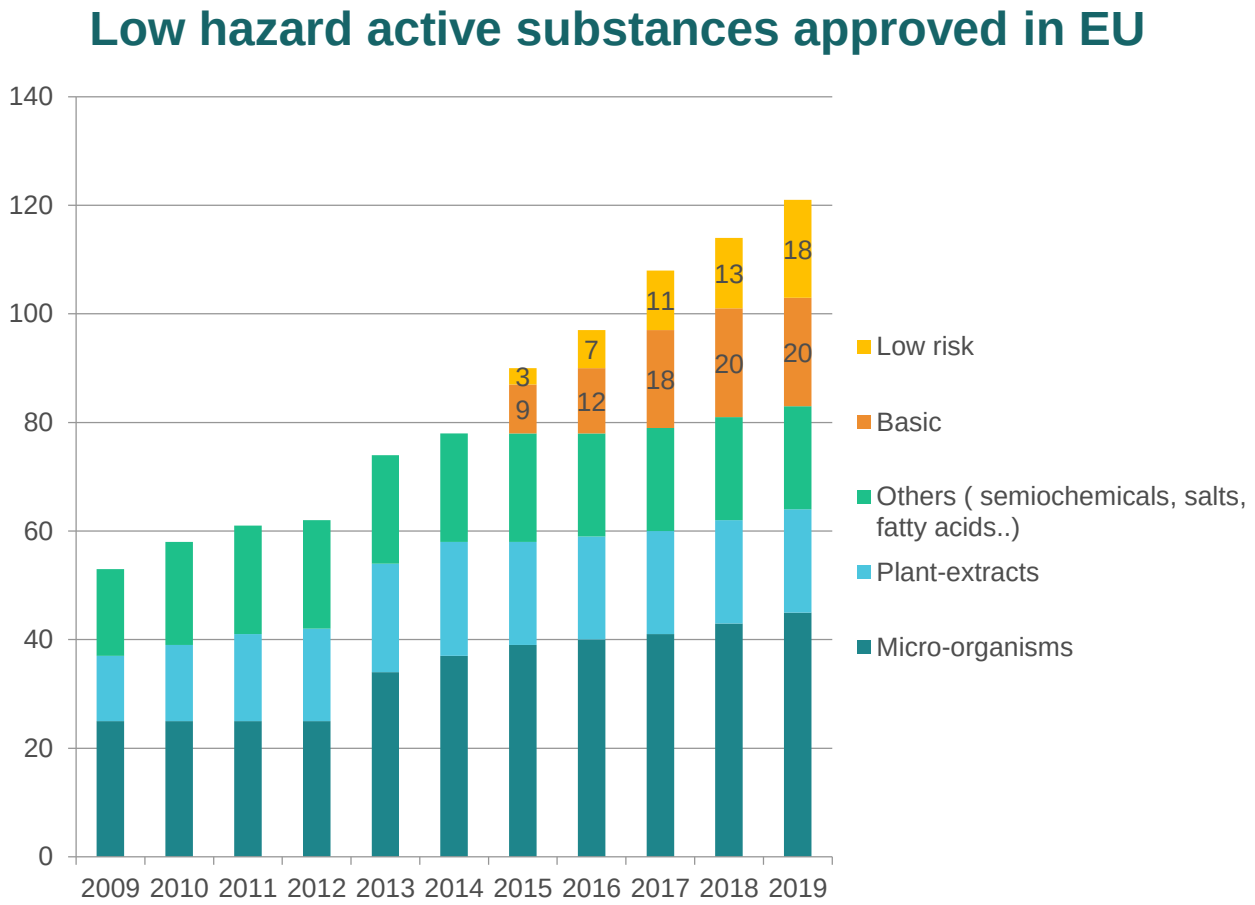
Increasing availability of biopesticides and microorganisms





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Initiatives on microbial plant protection products

- **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 microorganisms)

- **Guidance documents**:
  - ✓risk assessment of metabolites produced by microorganisms
  - ✓approval and low-risk criteria linked to antimicrobial resistance

- **Better Training for Safer Food**

Revision of concerned Regulations
Process – before ABIM 2019

- Q4 2018 – Q2 2019: identification and review of issues of the 3 Regulations
  - ✓ Data requirement cannot be technically met
  - ✓ Meaningfulness of data requirement
  - ✓ Technical inconsistency between Reg. and UP
  - ✓ Appropriateness of txt (in light of technical evolution)
  - ✓ Clarification/ interpretation issue
  - ✓ Lack of guidance
  - ✓ Inconsistency with guidance

- Q4 2019: BPWG start drafting of data requirements for microbial active substances

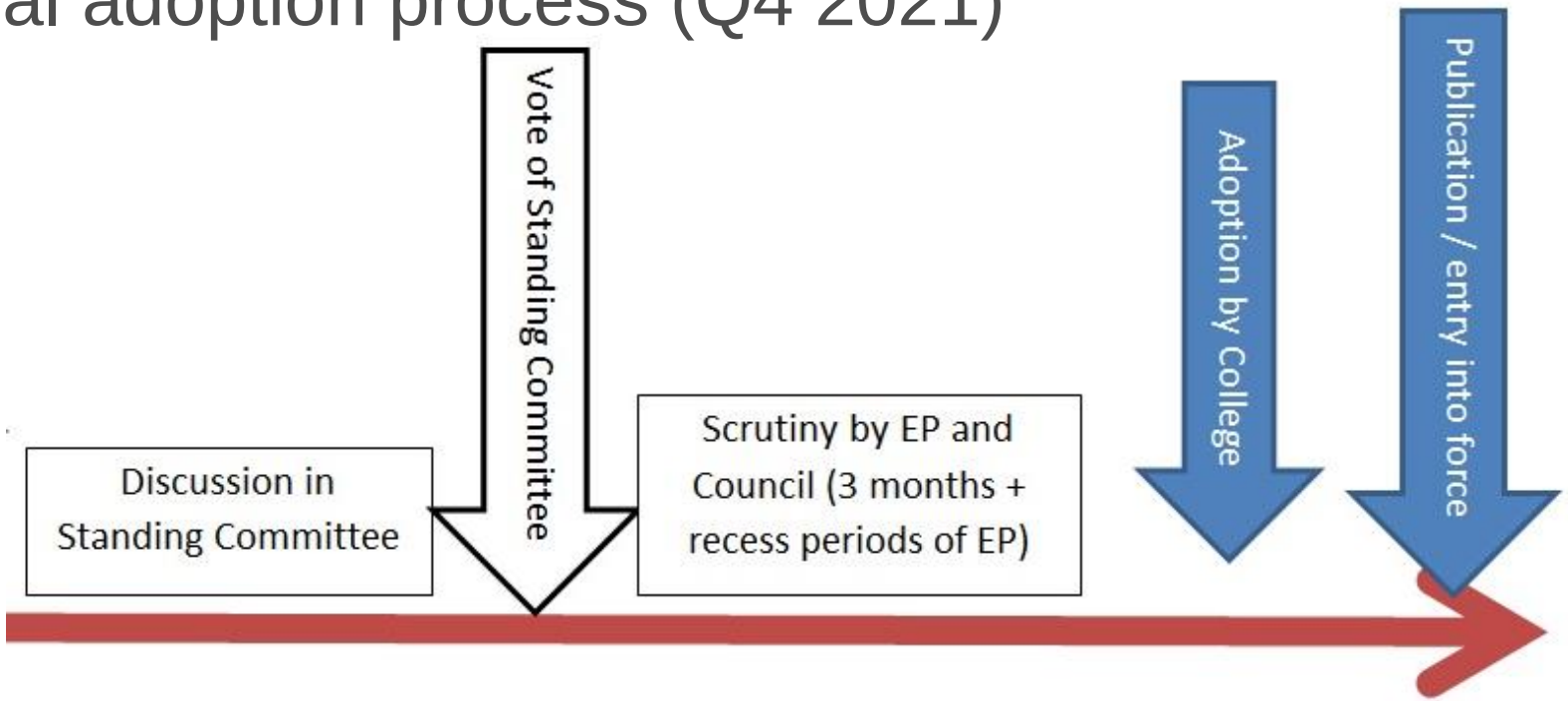
Revision of concerned Regulations
Process – after ABIM 2019

- Dedicated teleconferences for drafting data requirements for microbial active substances and PPP, and uniform principles
  - ✓ on data requirements for microbial active substances
  - ✓ on data requirements for microbial PPP
  - ✓ on uniform principles

- Biopesticides working group meetings
  - ✓ IBMA and ECPA contribution (e.g. decision tree, summary on sensitising potential of microbial PPP, statement on WGS)

Revision of concerned Regulations
Process – next steps

- PAFF (first discussion, Oct 2020 – Dec 2020)
- Consultations, not necessarily in this order, (2021):
  - ✓ EFSA panel
  - ✓ Stakeholders
- Formal adoption process (Q4 2021)



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Revision of concerned Regulations
Some technical contents

- 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 (see above)
  - ✓ Ecotoxicology studies (e.g. exposure/pathogenicity?)
  - ✓ Metabolites of concern (identification/exclusion of metabolites of concern)

Revision of concerned Regulations
Some technical contents

- 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

Guidance document on the risk assessment of metabolites produced by microorganisms

- OECD-based GD but EU-touch!
- Stakeholder consultation – May 2020
- Some technical contents:
  - ✓ Four stages
    1. Determination of assessment type
    2. Collection of basic info (Identification of "metabolites of potential concern")
    3. Determine "metabolites of concern" (exposure)
    4. Risk assessment
  - ✓ WGS
- Entry into force end-2021

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

- EU specific
- Stakeholder consultation – May 2020
- Some technical content:
  - ✓ Medically Important Antimicrobial only (i.e. WHO definition)
  - ✓ Two steps:
    1. WGS – screening known AMR genes
    2. Phenotypic approach - MIC

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

- Strain may not be approved, if:
  - ✓ AMR gene identified and present on mobile element = transferable
  - ✓ AMR gene identified and Phenotypic testing (Resistant) matches.

- Strain may be approved, if:
  - ✓ Phenotypic testing (Resistant) but this AMR gene not identified by WGS
  - ✓ AMR gene identified but not on mobile element and Phenotypic testing shows no resistance to this AMR
  - ✓ AMR gene identified but not on mobile element and Phenotypic testing shows resistance to this AMR for all strains of the same species (intrinsic resistance)

- Entry into force mid-2021

Low-risk substances and PPP

- Advantages
  - ✓ Longer approval period,
  - ✓ reduce timelines for review

- Assessment (Art.22 and Art.47 of Reg 1107/2009)
  - ✓ Generic VS specific risk mitigation measures
  - ✓ Hazard based criteria
  - ✓ Criteria specific to micro-organisms (AMR)

- Issues
  - ✓ Lack of awareness (e.g. at MS level or applicants have not explicitly applied for LR)
  - ✓ Applications including several uses (potentially LR and non-LR) for the same PPP
  - ✓ Sensitising potential for microorganisms

Better Training for Safer Food

Organization 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
  - ✓ Training activities for 2021-2022 (+2 more years)

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