Pacchetto Omnibus Food and Feed

Le novità per prodotti fitosanitari e biopesticidi

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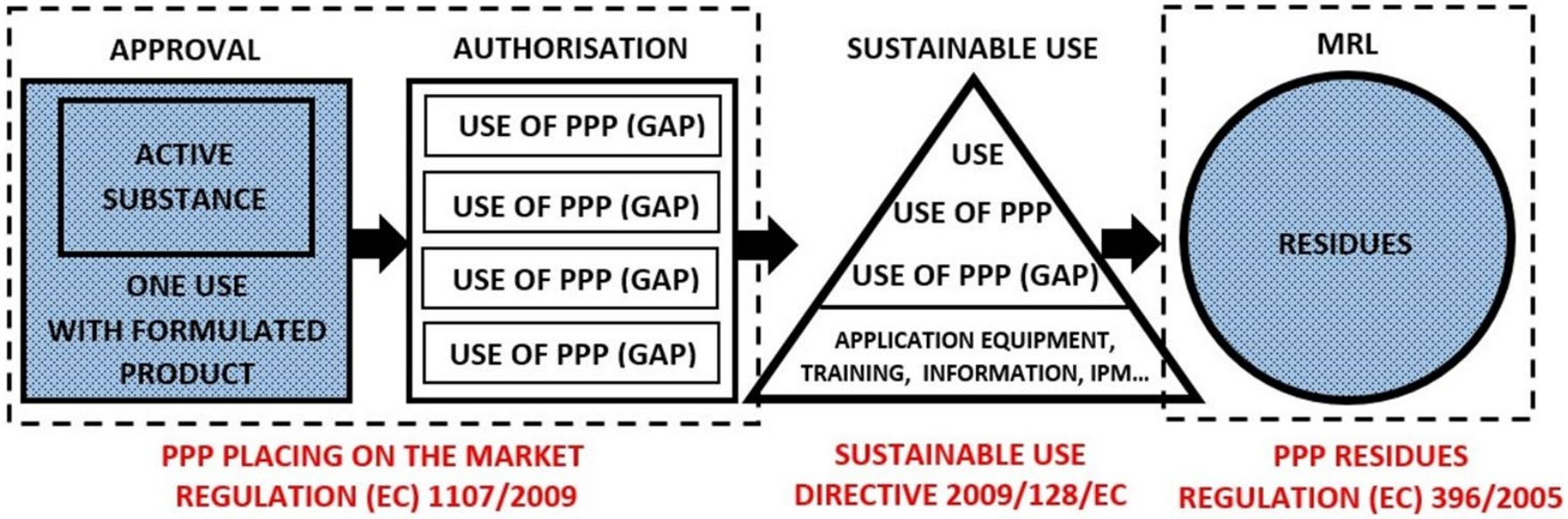
23 June 2026

1. Food and Feed Safety Simplification Package

2. Other ongoing/recent initiatives

European Commission

Pesticides are highly regulated in the EU



Several implementing regulations

Regulated at EU level

Regulated at Member State level

And other legislation e.g. Water Framework Directive, Drinking Water Directive, Groundwater Directive, Chemicals legislation: CLP, REACH

Objectives of Regulation (EC) No 1107/2009

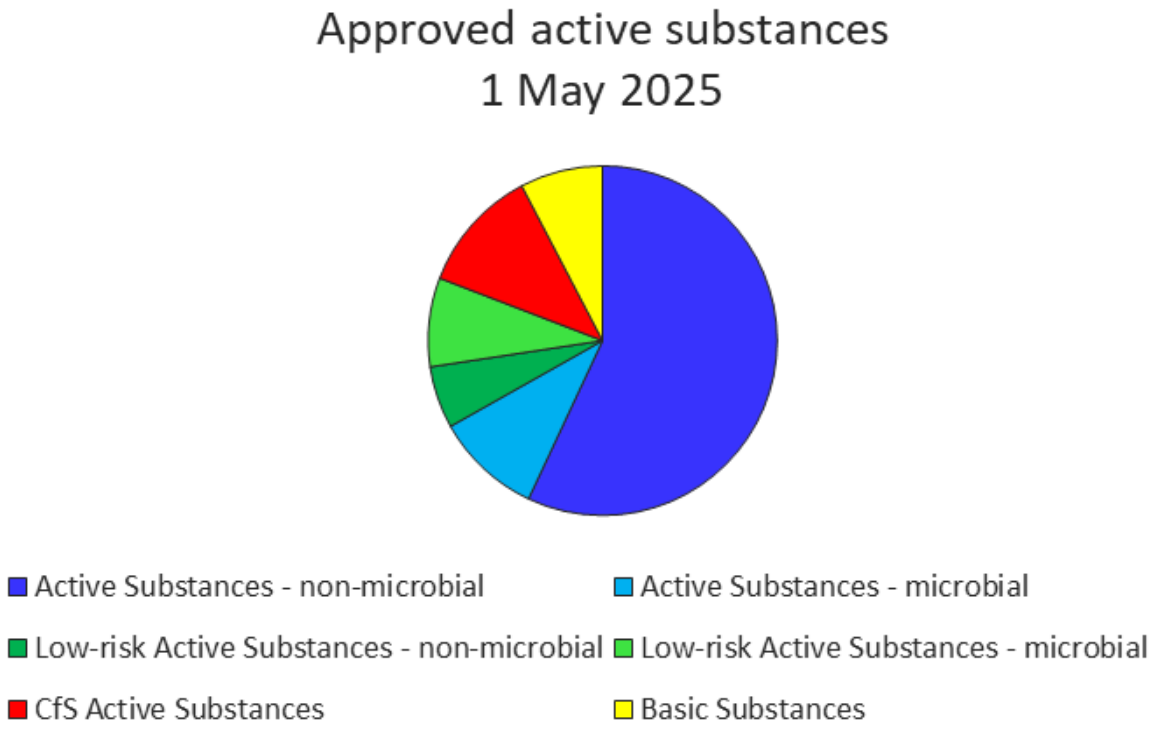
- **High level of protection** of human and animal health and the environment
- Increase **free movement** and **availability** of plant protection products

REFIT Report (20 May 2020):

- is effective in protecting human health and environment
- its efficiency and implementation could be improved (delays!!!)
- improving implementation (all stakeholders of the same opinion!)

https://food.ec.europa.eu/plants/pesticides/refit_en

Active substances – availability

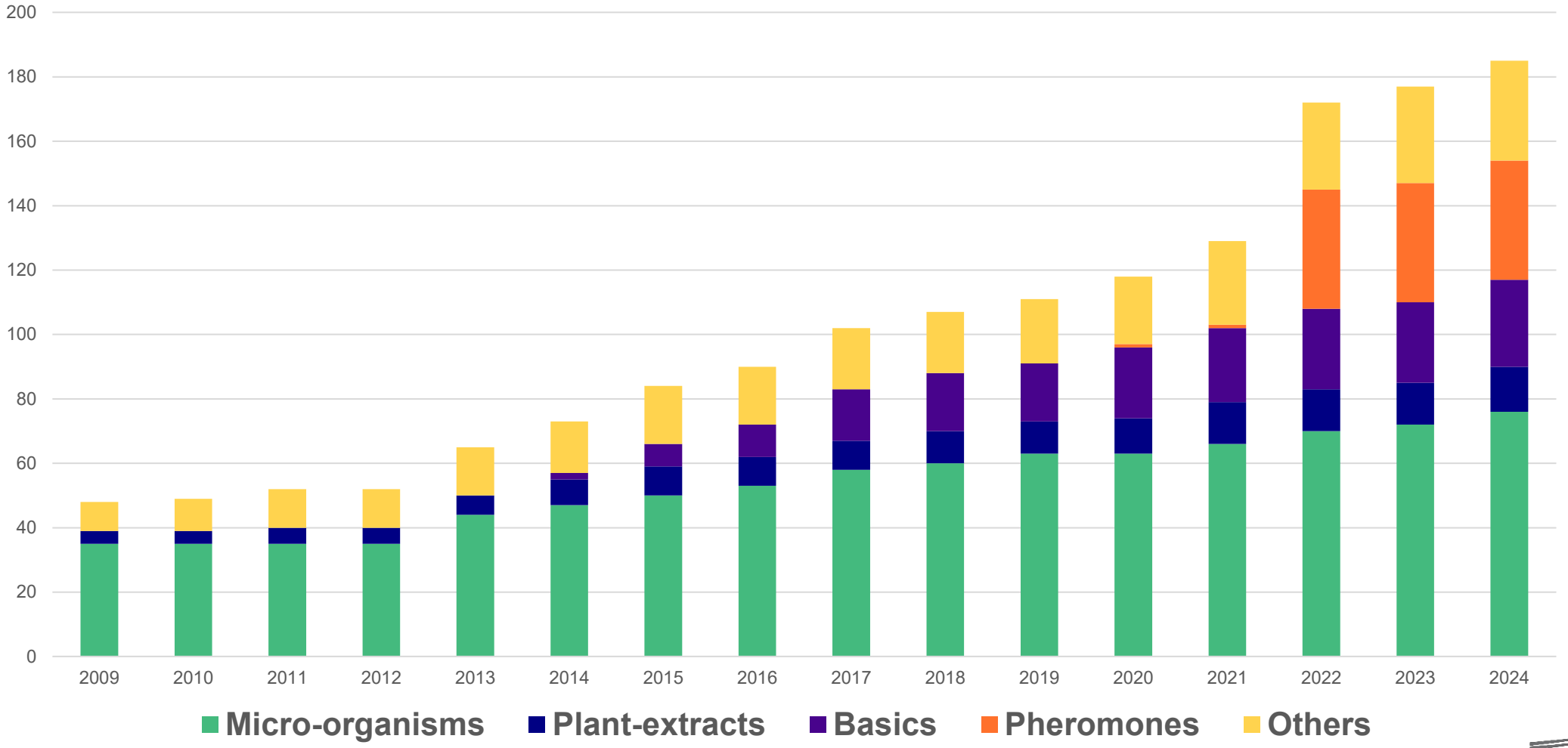


156 active substances that were approved under Regulation (EC) No 1107/2009 are no longer approved - ~2/3 due to lack of support for renewal

Total number of active substances approved in March 2026: 421

In recent years, a shift towards biological active substances in applications for approval of new active substances

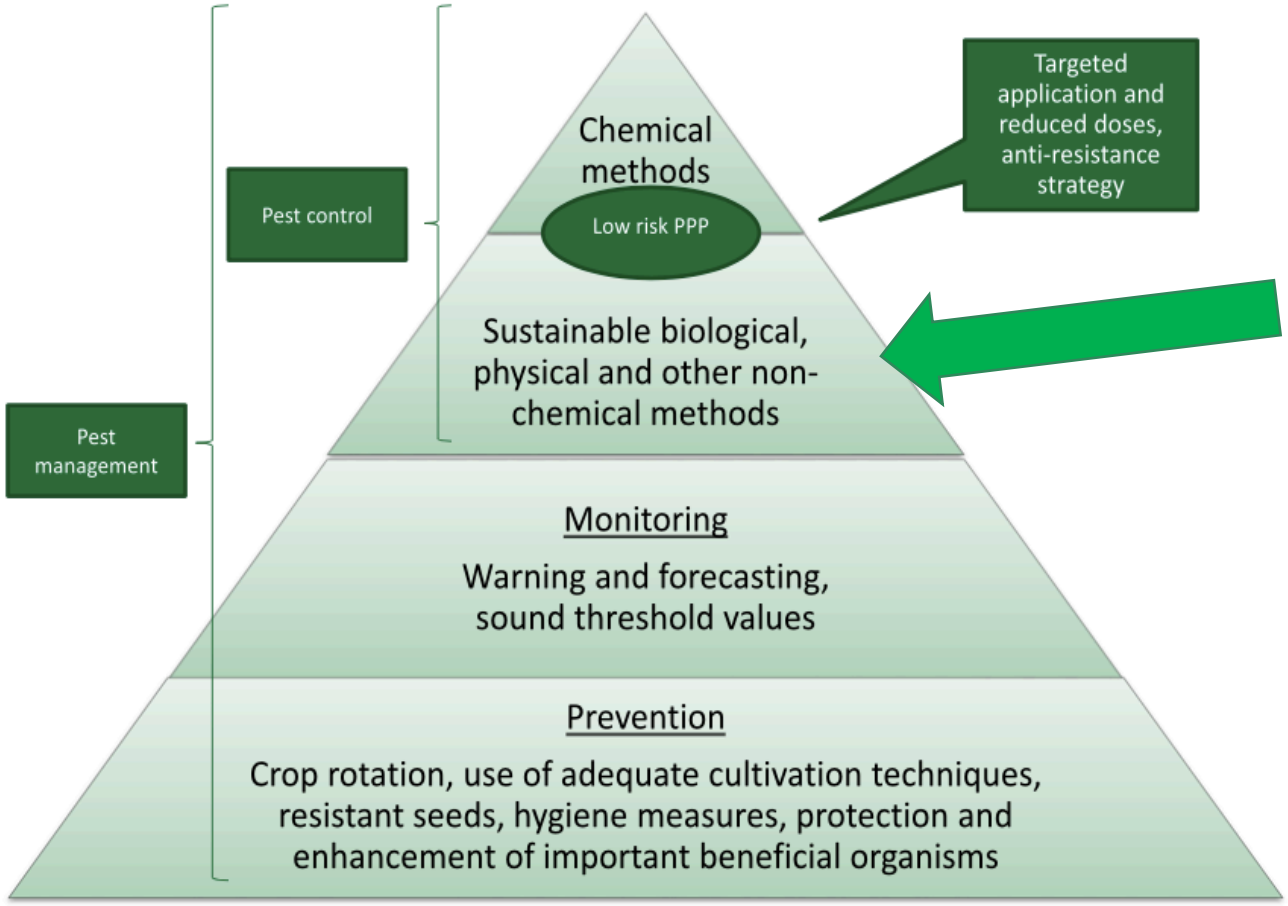
Availability of «low hazard» substances in the EU



A Vision for Agriculture and Food - biological control

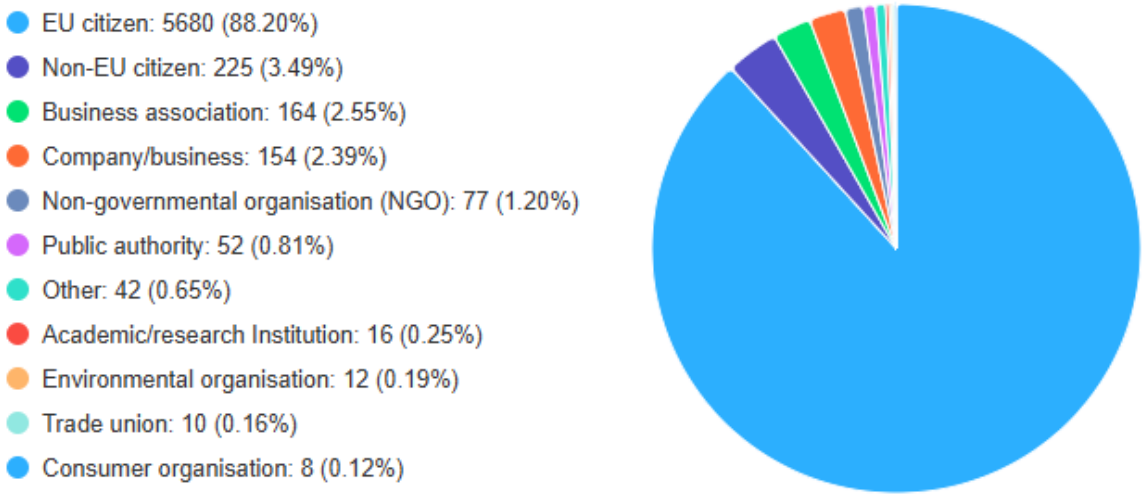
In 2025: a proposal for accelerating access to the market for biopesticides

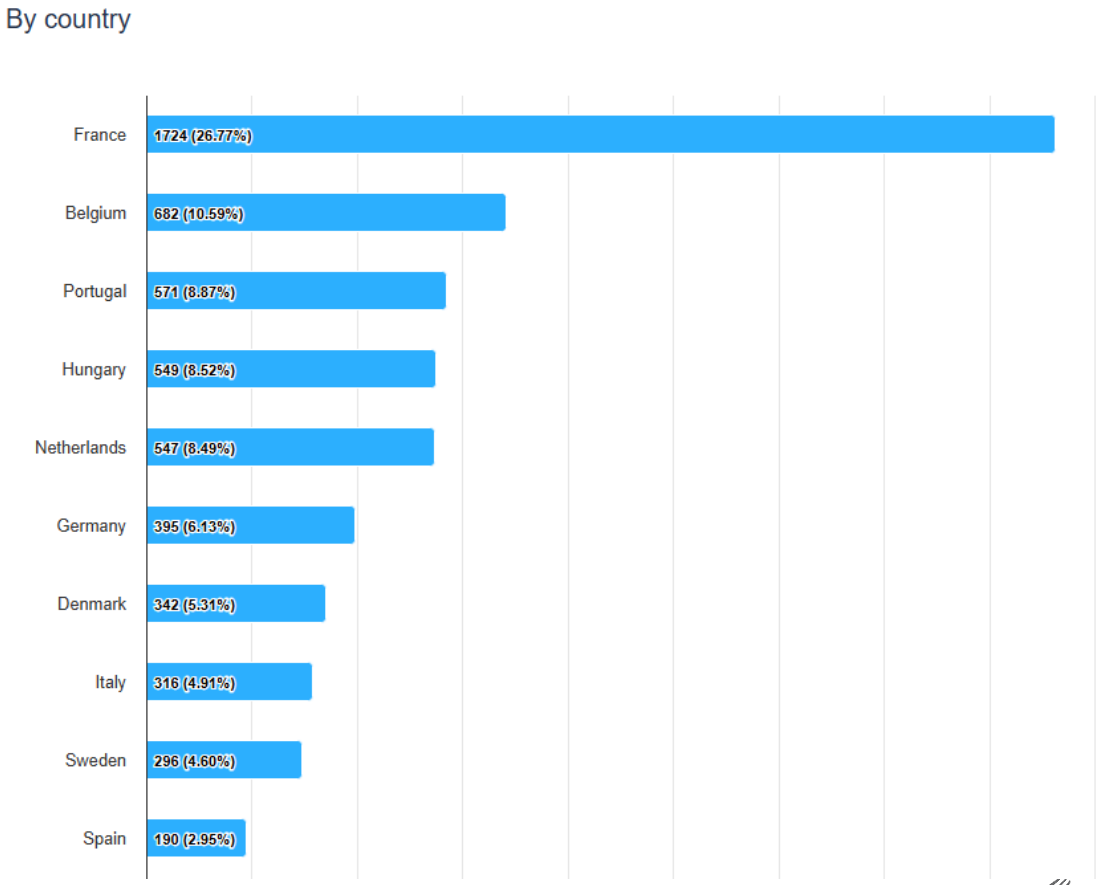
Proposal to be part of a a cross-cutting legislative simplification package of measures that deliver meaningful simplification in other policy areas than the CAP that affect farmers, the food and feed businesses and the related administrations



Call for Evidence - 16/09/25 - 14/10/25

- 6440 responses:
  - nearly 6000 from citizens following NGO-led campaigns
  - 318 from businesses (association)
  - 52 from public authorities
  - 16 from research instutions
  - 107 from NGOs





Food and feed safety simplification package

Goals

Contribute to overarching EC objectives:

- **Streamline and further harmonise** the EU regulatory framework
- **Increase competitiveness** and resilience of EU food and feed systems
- **Achieve the simplification targets** of reducing regulatory burden by 25% for companies and 35% for SMEs

Objectives

Faster access to markets and innovation under existing rules

Lower administrative burdens for economic operators and public authorities

Remove unnecessary complexity in risk management

Introduction of a definition of biocontrol substances (Article 3 of Reg (EC) No 1107/2009)

- Biocontrol active substances can be:
  - micro-organisms,
  - inorganic substances as occurring in nature (but no heavy metals and their salts), or
  - substances of biological origin or produced synthetically that are functionally identical and structurally similar to them
- Includes flexibility to maintain openness to innovation for substances “functionally identical and structurally similar” to those naturally occurring (e.g., pheromones, peptides, RNA)
- Fulfilling the definition is the basis for eligibility to other proposed advantages
- A rigorous risk assessment for human health and the environment will be maintained also for substances meeting the definition

Other amendments of Reg (EC) No 1107/2009 for biocontrol substances (I)

- **Biocontrol active substances are eligible for unlimited approval (Article 5)**
  - This is a change that can also concern chemical active substances
  - The need for a time-driven re-assessment of all active substances in the current Regulation takes up most of the resources in Member States.
  - Processes are often (significantly) delayed
  - Freeing Member States resources will create capacity to process applications for new (biocontrol) active substances
  - Several safeguards will ensure that renewal process are more agile and will focus on substances where new evidence indicates that there is a need for verification, ensuring high safety standards are maintained over time

- **Possibility for EFSA to assume the role of rapporteur Member State (Article 7)**
  - Increasing capacity to process applications for new biocontrol active substances – EFSA to get additional human and financial resources for this new task
  - Reducing queues for potential applicants
  - Reducing costs as EFSA will not charge fees

Other amendments of Reg (EC) No 1107/2009 for biocontrol substances (II)

- **Fast-track for assessing applications for new biocontrol substances (Article 11) and for plant protection products containing them (Article 37)**
  - rapporteur Member States shall give priority to the assessment of applications for approval of new biocontrol active substances and for the authorisation of plant protection products containing them
  - Currently done only in a few Member States where national law allows, this amendment intends to enable all Member States to establish fast track lanes for biocontrol

- **Possibility for Member States to grant provisional authorisation for plant protection products containing new biocontrol active substances while approval procedures are still ongoing (Article 30)**
  - 90% of EU biocontrol manufacturers are SMEs: need for fast return on investment and quicker time to market
  - Safeguards: granted for maximum 5 years, and only if a first assessment concluded that approval criteria are expected to be met

Other amendments of Reg (EC) No 1107/2009 on biocontrol substances (III)

- **Reinforced zonal authorisation and mutual recognition (Articles 3, 37 and 42)**
  - All Member States are considered to be in one zone for biocontrol product authorisations (Art 3) – reduces burden on companies and authorities for applications as one Member State can become the reference Member State for all
  - Tacit agreement to applications for mutual recognition of authorisations if decisions are not taken within the regulatory limit of 120 days

- **Exemption from record keeping obligations for biocontrol products (Article 67)**
  - All professional users of plant protection products must keep detailed records of each use
  - Exemption for plant protection products containing only biocontrol active substances would reduce burden for farmers and increase attractiveness of use
  - Would address also difficulties to have meaningful statistics by merging data from chemical pesticides (e.g., expressed in kilogrammes, litres etc) and data on biopesticides (expressed in specific biological units)

Overall impacts & cost-savings

LEAN, FASTER SYSTEMS LEAD TO SUBSTANTIAL SAVINGS

- Abolishing systematic renewals of approvals/authorisations contributes most.
- Streamlined procedures & risk-based controls also reduce administrative burden.
- **Cost savings:**
  - **€428 m/year (businesses, including €227 m/year for SMEs) +**
  - **€661 m/year (public authorities)**
  - **= > €1 billion/year**

CLARITY & PREDICTABILITY WITH A FOCUS ON RISK & ENABLING INNOVATION

- Remove grey zones or duplications as provisions are clarified.
- Faster time-to-market for innovative solutions: **SMEs benefit most**.
- Safety levels remain unchanged.
- Science-based assessment continues + review & withdrawal powers remain.

1. Food and Feed Safety Simplification Package

2. Other ongoing/recent initiatives

Other ongoing/recent initiatives (i)

- Guidance document on **Metabolites of Concern** (2020, amendment ongoing)
- Guidance document on **AMR** (2021, amendment ongoing)
- Commission communications with **list** of recommended test **methods/ guidance documents** (2023, amendment ongoing)
- **Explanatory notes** to the data requirements (2023, amendment ongoing)
- GD on **baculoviruses** and **bacteriophages** (2026)

Other ongoing/recent initiatives (ii)

- Systematic reviews to facilitate dossier preparation on microorganisms
  - ✓ Group review/ Background levels (2025)
  - ✓ consensus documents (ongoing)
  - ✓ Sensitising potential (ongoing)

- OECD Expert Group on Biopesticides guidance documents (e.g., ongoing work on Problem Formulation on micro-organisms)

- EFSA guidance documents (e.g., (i) characterisation of micro-organisms, (ii) scientific report on fit for purpose risk assessment for low concern active substances and uses)

Thank you for your attention!

For further informationen:

https://ec.europa.eu/food/plant/pesticides

https://food.ec.europa.eu/horizontal-topics/simplification-legislation_en

Disclaimer: All views expressed are purely personal and cannot be considered the official position of the European Commission.