Regulation 1107/2009 – update and ongoing developments

PESTICIDE STEERING NETWORK (EFSA)

11-12 NOVEMBER 2025

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Outline

- New or upcoming legal/regulatory requirements
- Guidance development
- Feedback from decision making on AS (feedback from PAFF)
- Other hot or important topics

Safeners and Synergists: Commission Regulation 2024/1487

Entry into force: 19 June 2024

New requirements:

- Setting data requirements (Art 25) – Annex III lists specific DR on efficacy, *otherwise like AS!*
- Establishing the work programme (Art 26) – Annex I to be amended – **10 substances**

Dates to keep in mind:

- Submission via IUCLID (available in April 2026). Shared submissions preferred.
- For notified S&S (work programme): Dossier submissions latest 48 months from the date of entry into force - i.e. by 19 June 2028 - S&S not notified can no longer be on the market
- New S&S dossiers can be submitted at any time (free RMS choice)
- Transitional period for products already on the market: until 5 years of the adoption of that work programme – 19 Dec. 2030

https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists_en#safeners-and-synergists

Update of the data requirements (DRs) and Uniform Principles (UPs)

- Update of the DRs (Implementing Regulations 283/2013 and 284/2013) and the UPs are ongoing (advanced state) – **NOT A FULL REVIEW**
- Key changes:
  - reflect new GD on bees, birds & mammals, water treatment processes
  - biological substances - clarification on the type of substances where certain data may be exempted (if well justified)
  - Reinforcing the use of NAMs
  - strengthening information requirements for co-formulants and the assessment of developmental neurotoxicity (DNT)
- Feedback (public consultation) was held – ended on 9 October 2025
- Transitional measures – 2 years
- Possible vote in December 2025 PAFF
- Scrutiny by Council and EP after vote at PAFF (3 months)

Co-formulants in PPPs

- Negative listing (different from positive listing of active substances)
- List of **unacceptable co-formulants Reg. 2021/383** (Annex III of Reg 1107/2009) → 144 unacceptable substances listed
- Regulation 2023/574 sets the criteria & procedure to amend Annex III
  - Mostly based on hazard properties
  - Criterion 10 (safety net – other reasons)
- On-going amendment of Annex III; ~14 new substances to be added
- Guidance under preparation for the assessment of PPPs, including co-formulants
- Work to establish a common database of co-formulants ongoing
- https://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/assessment-plant-protection-products-ppps_en

Co-formulants in PPPs – ongoing work on EU list of co-formulants

EU list of co-formulants to facilitate assessments:

- **Short-term solution**: The Commission is developing a list/database of co-formulants used in Member States; so far, nine Member States and EFSA have submitted their lists.
- A merged list has been **provided to ECHA** under a service contract:
  - ✓clean and analyse the list
  - ✓providing details on each substance such as its registration status in REACH, associated tonnage, and involvement in any REACH processes like screening or evaluation
  - ✓note exemptions from registration and their reasons
- This list (~3000 co-formulants) from ECHA is **expected by early 2026**

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Co-formulants in PPPs – next steps

- Following the work by ECHA, the Commission, in collaboration with Member States, ECHA, and EFSA, intends to **prioritise** data-poor co-formulants for further review.
- **Mid-term:** guidance document and a new EU co-formulant database to aid in the harmonisation of PPP assessments; EU list of the co-formulants and feedback on earlier drafts and a recent two-page outline will guide further development.
- Finalise a **note on data sharing between MS** - outlines that Member States can share co-formulant data among themselves – possible endorsement at the December 2025 PAFF (needed for harmonisation)
- Notification of unacceptable co-formulants: development of a standard template for notifications under consideration.

New CLP hazard classes

- New CLP hazard classes: ED, PBT, vPvB, PMT, vPvM - more substances, including co-formulants, will be classified
- Work to align Annex II of Regulation 1107/2009 is ongoing
- Dates of application: https://echa.europa.eu/new-hazard-classes-2023
- **Active substances placed on the market from 01/05/2025** – New classification and labelling mandatory. *DAR/RAR for applications received after this date should include the new hazard classes – MS can also apply to ongoing files, if feasible, or submit a CLH to ECHA outside of approval/renewal*
- 01/11/2026 for substances already on the market on 01/05/2025 (need to update the label, or stop the supply of old stock after 01/11/2026);
- **Mixtures (PPPs) placed on the market from 01/05/2026** – New classification and labelling mandatory.
- 01/05/2028 for mixtures already on the market on 01/05/2026 (need to update the label, or stop the supply of old stock after 01/05/2028).

Implementing Regulation (EU) 2023/564 – electronic record keeping of PPP use

- Content of the records given in Article 67 is specified technically in an Annex
- Records as of 1st January 2026 have to be available in electronic format within 30 days of the use
- Interim arrangements: for uses before 1st January 2030 MS may provide longer periods as long as the records are available in electronic format no later than 31st January of the year after the use
- Interim arrangements: for uses before 1st January 2027 Member States may allow that the respective records are not transferred into the prescribed electronic format (new provision Implementing Regulation (EU) 2025/2203)

Draft for new labelling requirements for Plant Protection Products (PPP) - main changes

- Inclusion of a **digital label** → Has to contain the same elements as the physical label!
- Inclusion of **additional phrases** to communicate the risk mitigation measures to protect human health and the environment
- Inclusion of **phrases** related to the risk mitigation measures that should be applied **when sowing treated seeds**
- A **pictogram** to communicate **potential hazard** of a plant protection product **to pollinators** (where applicable)
- Precautionary **sentence** to warn about the **potential of micro-organisms to provoke sensitising reactions**

Draft for new labelling requirements for Plant Protection Products (PPP) - possible timelines

- The new labelling requirements will not apply immediately after the vote by Member States (in PAFF Committee)
- Subject to scrutiny of EP + Council, if no objection entry into force foreseen for the mid of 2026 (current planning, subject to change)
- No **triggering of automatic re-labelling of all existing products** on the European market
- Will apply to the **label of products where the application for (renewal of) authorisation is submitted after 1 January 2027** *(date still under discussion)*
- Transitional measures for existing PPPs and applications
- The **current labelling Regulation** (EU) No 547/2011 **will be repealed**

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- New / upcoming GD
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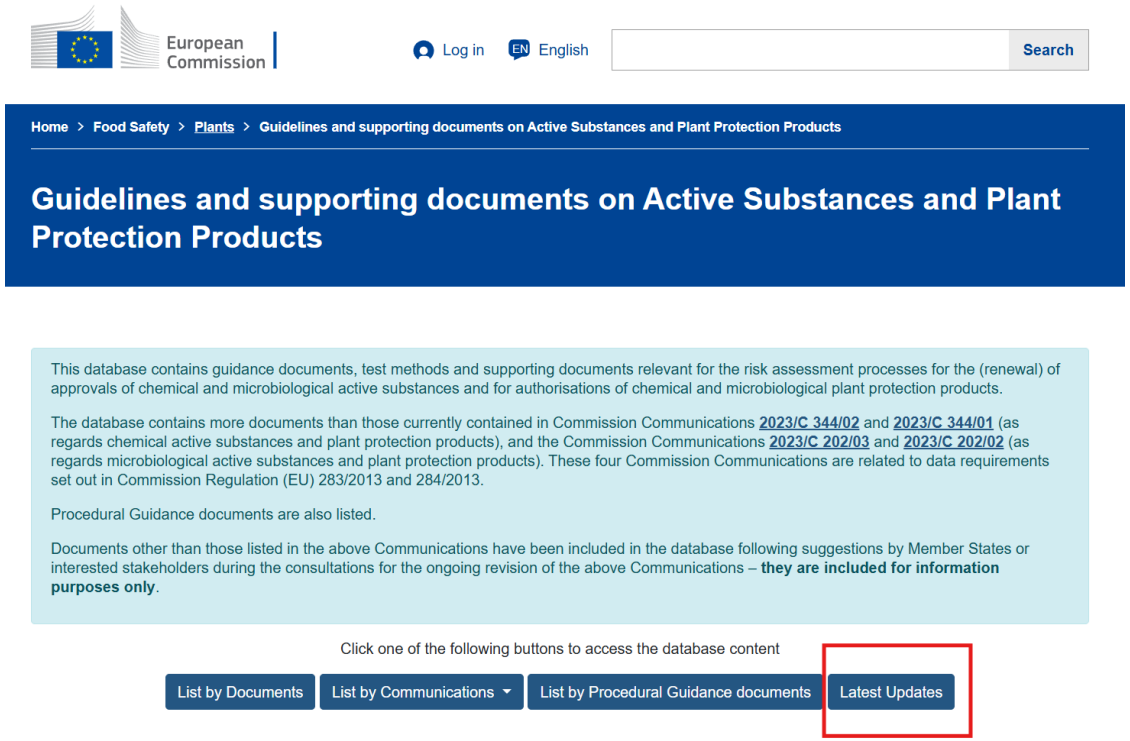
Database of GD - latest update

- Database contains guidance documents, test methods and supporting documents relevant for the risk assessment processes for the (renewal) of approvals of chemical and microbiological active substances and for authorisations of chemical and microbiological plant protection products
- 3 search options – by document title, by Communications or by procedure
- Users can report errors via a feedback form under each item in the database
- New feature: Latest update (if new document or a new version of existing document uploaded)



GD and studies on microorganisms

Completed

- Group review and background levels on species of micro-organisms (completed 2025)

Ongoing

- GD on viruses
- GD on AMR
- GD “explanatory notes on data requirements on MO”

Planned (2026)

- Consensus document on MO
- GD on metabolites of concern
- Commission Communications (list of test methods/GD)

GD on water treatment processes

- Guidance on the impact of **water treatment processes** on residues of active substances or their metabolites in water abstracted for the production of drinking water – Endorsed March 2024
  - Applies to applications submitted **on or after 1 April 2026**.
  - *Applicants may use the guidance for applications submitted before that date*
- Applicable also for **confirmatory information** requests previously established and linked to the agreement of guidance:
  - The Commission wrote to concerned applicants (+ RMS/co-RMS) to inform that the deadline for submission is **20 March 2026**
  - For 6 active substances, there will be an overlap between CI and renewal assessments – duplication to be avoided. Case by case.

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Update GD on birds and mammals

- Revised guidance for **birds and mammals** (endorsed October 2024) - applicable for applications for a.s. and PPPs submitted from 1 October 2025

- PAI endorsed an approach for PPPs – available on public part of CIRCABC:

  ➢Bench Mark Dose (BMD): until the BMD for the active substance concerned has been derived at EU level (in particular as part of the approval or renewal of approval of the active substance) the NO(A)EL will be used

  ➢Time Weighted Average factor (fTWA): The decision, if the TWA may be used, is to be made/assessed by one MS on behalf of the other MS of the EU. To set the fTWA, the procedure described in the GD on the evaluation of new data on an active substance submitted post (renewal of) approval (GD SANCO/10328/2004-rev 10) is to be followed.

GD currently under preparation/revision or discussion in PAFF

Under preparation/revision:

- Updated guidance on emergency authorisations
- Negligible exposure –stakeholder consultation finished. Final draft under preparation
- Non target arthropods, soil organisms, non-target plants
- Indirect effects on biodiversity
- OPEX GD (closed transfer systems)
- Update of the GD on the evaluation of new data on an active substance submitted post (renewal of) approval (SANCO/10328/2004)

Under discussion for endorsement in PAFF:

- Revised guidance on bees (after amendment of DR & UP)

SW FOCUS scenarios – choice of the temporal percentile

- 2016: COM mandated EFSA to undertake a ‘repair action’ of the FOCUS surface water scenarios, the associated guidance and calculation tools. Request to introduce into all FOCUS scenarios a 20-year assessment (rather than the current 16 to 18-month assessment period) = more representative meteorological data!)

- 2020: EFSA delivered the outcome of the mandate - a decision is required from risk managers on what temporal percentile of the new meteorological data should be used to model the concentration of the substance in surface water.

- Now: Process to decide on the temporal percentile put forward by COM, liaising with EFSA:
  - January 2026: info session chaired by EFSA for risk assessors and risk managers of MS. Stakeholders will be also invited to stay informed.
  - Feb 2026: 2nd info session only with MS chaired by the COM to ask for their preliminary positions on the temporal percentile
  - PAFF March 2026: *possible* endorsement of one of the percentiles by risk managers
  - EFSA will implement the value in the models and use them

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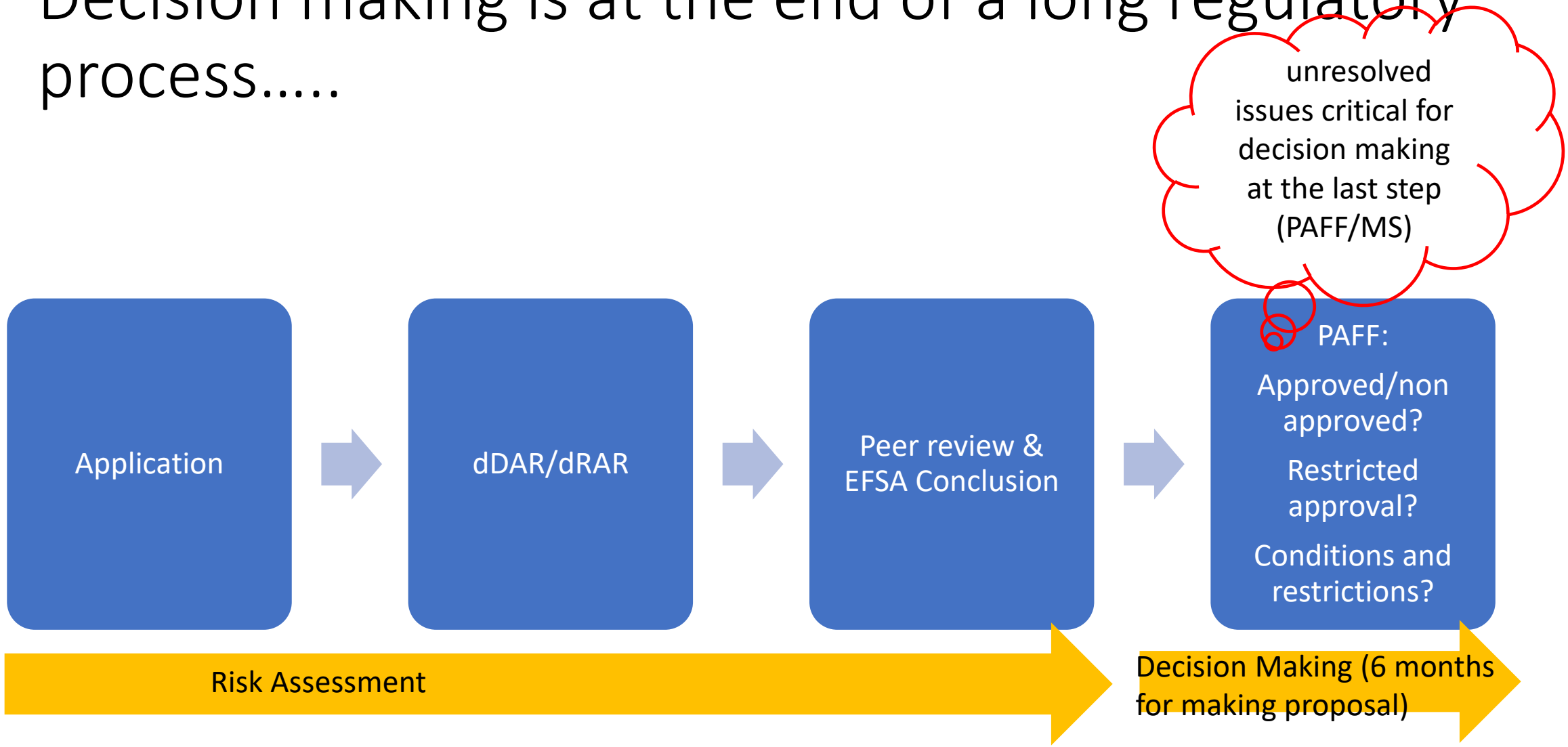
Decision making is at the end of a long regulatory process…..



Standing Committee PAFF

- „difficult“ regulatory decision making is sometimes caused by:
  - No consideration of lower end of the GAP (if GAP a range)
  - No consideration of risk mitigation measures – follow up questions, now in light of the Compendium
  - „natural“ AS assessed with a RA which might not be the most appropriate for this kind of AS (e.g. pelargonic acid, rape seed oil, sulphur)
  - Need for consideration of PPP for representative use (including co-formulants)

→ **triggers follow up questions to EFSA and RMS (and peer review)!**

Assessment of alternative AS – be prepared

- Applications for AS with new modes of action „in the pipeline“
  - bacteriophages
  - peptides
  - RNAi
  - …

The current „schemes“ may not fit – ad-hoc & „need to know“ RA may be needed

Pre-submission meetings important!

Take home message from RM to peer reviewers

- Alternative PPPs are needed for the farmers toolbox : please give priority to new active substances
- Use problem formulation and need to know approach – make good use of pre-submission meetings in particular for such innovative NAS and MO
- BEFORE finalising peer review
  - make sure all information is considered in the peer review (consider weight of evidence & expert knowledge),
  - consider RMM and lower range of GAP to see if there is a safe use
- Avoid delays (during peer review and the next steps - fit for purpose output needed!)

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PFAS active substances

As of 1 November 2025, **30 PFAS active substances** (OECD definition) are approved under Regulation (EC) No 1107/2009, of them:

- 9 are Candidates for Substitution
- 2 do not contain the C-CF3 moiety

For 24 the renewal process is on-going and for six the renewal process will start in the future (for two of them in 2026) – EFSA Conclusions are available for 3, 11 are with RMS and 10 in peer review.

As a result of the strict criteria in the EU legislation on, in the past decade ~20 PFAS active substances have been removed from the EU market – either by expiration of approval due to lack/withdrawal of renewal application (most recently penthiopyrad) or due to non-renewal decisions (most recently triflusulfuron and flufenacet).

TFA – context

- It is widely recognised that **TFA is a 'substance of multiple sources' -** refrigerants and blowing agents (atmospheric deposition via precipitation), industrial output, municipal wastewater, liquid manure, PPPs and others all contribute to environmental exposure.
- **Exposure routes may vary** between Member States and even within areas of individual Member States - depending on the nature of agriculture, industry etc. **TFA found in areas where there is no PPP use**.
- Swiss groundwater monitoring: *"exceptionally high peak values of over 10 µg/l were recorded at two neighbouring monitoring sites located near a watercourse that also contains treated industrial wastewater".*
- A 2024 report from Denmark concluded that precipitation contains TFA at a concentration between 0.2 – 1 µg/L and therefore is a major source of groundwater contamination.
- **PPPs are thus not the only source of contamination**. However, it is recognised that they play a role in contamination and therefore it is essential to fully assess and carefully regulate their use.

TFA – ongoing activities

- The process for **harmonised classification and labelling** for TFA is ongoing in ECHA – legal deadline for the RAC Opinion is 26 October 2026
- The Commission mandated EFSA to **re-assess the toxicological reference values** for TFA. A public consultation on the draft assessment was already carried out. The Commission has also sent a second mandate to both EFSA and ECHA, focused on the **formation of TFA in soil and water**
- The Commission has signed an agreement with the World Health Organisation to **determine the relevant PFAS in drinking water** and recommend health-based values for those relevant PFAS
- In parallel, the Commission launched a study to analyse **treatment techniques** and their related costs for PFAS (and TFA) removal from drinking water

Food and feed safety simplification omnibus

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

Targeted simplification for safer, smarter, and more competitive food systems

CLUSTER 1 -> FASTER ACCESS TO MARKETS AND INNOVATION UNDER EXISTING RULES

Regulation (EC) No 1107/2009 – Biocontrol package

Directive 2009/128/EC - Aerial spraying of PPP

CLUSTER 2 -> LOWERING ADMINISTRATIVE BURDENS

Regulation (EC) No 1107/2009 – Simplification beyond biocontrol

Regulation (EU) No 528/2012 – Biocidal Products Regulation (BPR)

Regulation (EC) No 396/2005 – Maximum Residue Levels (MRLs)

Regulation (EC) No 1829/2003 – GMM fermentation

Regulation (EC) No 1831/2003 – Feed additives

Regulations (EC) Nos 852/2004 & 853/2004 – Notification of national hygiene measures

Regulation (EC) No 1099/2009 – Depopulation reporting

Directive 98/58/EC – Record-keeping for farmers (medicinal treatments & mortalities)

CLUSTER 3 -> REMOVE UNNECESSARY COMPLEXITY IN RISK MANAGEMENT

Regulation (EC) No 999/2001 – BSE rules

Regulation (EU) 2017/625 – Official Controls Regulation (OCR)

Targeted amendments

- Biocontrol (as announced in the Vision for Agriculture and Food):
  - Clear definition of biocontrol active substances
  - Priority assessment by Member States of both approval of new active substances & authorisation of products containing them, with one-zone system to avoid duplication
  - Fast-track and provisional authorisations, reinforced mutual recognition
  - Optional EFSA role in risk assessment (requires extra resources)
- Mutual recognition
- Data protection
- Treated seeds
- Increasing efficiency of approval and authorisations procedures

Actions taken and next steps

- Some targeted stakeholder consultations already held. Views of Member States and stakeholders are being taken into account
- Call for Evidence already held (DL: 14 October 2025)
- Staff Working Document (justification of measures)
- Further internal discussion and validation of further simplification ongoing
- Inter-service consultation to be carried out
- Foreseen adoption of the proposal by end of 2025

Thank you for your attention

For further information:

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

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