Regulation 1107/2009 – update and ongoing developments

PESTICIDE STEERING NETWORK

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Outline

- New or upcoming legal/regulatory requirements
- Guidance development
- PFAS/TFA
- Update on the Food and Feed Safety Simplification Proposal
- Feedback from risk managers

Safeners and Synergists: Commission Regulation 2024/1487

- Submission via IUCLID (template available from 27 April 2026). Shared submissions preferred
- For the 10 notified S&S in the work programme (Commission Regulation (EU) 2025/2274): 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 placed 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 Regulation (EU) 2025/2274 which adopted the work programme – 3 Dec. 2030
- WG on efficacy of S&S initiated in April 2026

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

- Feedback (public consultation) was held – ended on 9 October 2025
- Some further comments from MS received and considered since then
- New final texts presented to Member States for the May 2026 PAFF
- Transitional measures – 2 years
- Possible vote in June 2026 PAFF
- Scrutiny by Council and EP after vote at PAFF (3 months)
- Once the DR and UP are adopted, the EFSA Bee GD (2023) can be endorsed

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; 12 new substances to be added (voted in December 2025, adoption procedure in progress); 3 new notifications from Member States submitted since December 2025 (as of 07/05/2026)
- 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: nine Member States and EFSA submitted their lists.
- A merged list was **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) was delivered by ECHA in early 2026; refined to ~2200 by COM
- An ad hoc meeting with the contributing MS, EFSA and ECHA was held on 27 March, where the work performed was explained
- Another meeting with all MS, EFSA and ECHA, will be held on 5 June.

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/information limited co-formulants for further review.
- **Mid-term:** guidance document and a new EU co-formulant database to aid in the harmonisation of PPP assessments
- A **note on data sharing between MS** - outlining that Member States can share co-formulant data among themselves was endorsed at the December 2025 PAFF.
- **Notification of unacceptable co-formulants**: development of a standard template for notifications under consideration.

New CLP hazard classes – alignment work

- **Discussions** to align Annex II to Regulation 1107/2009 and the new hazard classes established in the CLP Regulation are **on-going** with Member States**.**
- **Endocrine disruptors (ED)**: known or presumed (category 1) and suspected (category 2), both for human health and for the environment → **Very close correspondence** between the currently identified **ED under Regulation (EC) No 1107/2009** and **category 1.**
- Transfer of ED substances (EFSA) to Annex VI of CLP (as ED 1) is ongoing.
- **Assessment of ED:**

- For **applications submitted after 11 June 2025**, RMS should include ED as part of a CLH proposal, along with other hazard classes, and submit to ECHA. Amendment of Article 11(9) of Implementing Regulation 2020/1740 to formalise this obligation to be done.
- For **applications submitted before 11 June 2025**: ED should be assessed either as part of the approval/renewal procedure or as part of the CLH proposal. It is the choice of the RMS. If the former, any identification as ED will be added to CLP once the decision on the approval/renewal of approval is made. If the latter, the RMS needs to flag it to ECHA's RAC secretariat (or in the notification of its intention).

New CLP hazard classes – alignment work

- **Persistent, bioaccumulative, toxic (PBT) / very persistent, very bioaccumulative (vPvB)** → The criteria under **CLP regulation correspond roughly** to those under **Regulation (EC) No 1107/2009**, but are **more conservative.** Discussions **if and how** alignment can be done.
- **Scientific justification** to calculate **persistence** the same way for **synthetic organic chemicals and** for the **chemical elements and their inorganic compounds**, especially for those that occur in nature is **very questionable.**
- **Persistent, mobile, toxic (PMT) / Very persistent, very mobile (vPvM)** → **Persistence** and **mobility** are key parameters to **calculate Predicted Environmental Concentrations (PEC)** of **active substances and their relevant metabolite** under **Regulation (EC) No 1107/2009.** Alignment to the new hazard classes will be **a step back,** *because the* current approach provides **more realistic** estimates of the environmental fate and behaviour of substances and the risk they pose.

New labelling requirements for Plant Protection Products (PPP) - main changes & timelines

- Scrutiny period ended. No objections. Regulation will be published soon.
- Main changes: **digital label (**to contain the same elements as the physical one), **new phrases** to communicate the risk mitigation measures to protect human health, the environment (including **when sowing treated seeds)** & **pictogram** to communicate **potential hazard** of a product **to pollinators.**
- Will apply to the **label of products where the application for (renewal of) authorisation is submitted after 1 January 2028.**
- No **triggering of automatic re-labelling of all existing products** on the European market. Transitional measures for existing PPPs and applications
- The **current labelling Regulation** (EU) No 547/2011 **will be repealed**

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GD and studies on microorganisms

Completed

- Group review and background levels on species of micro-organisms (completed 2025)
- GD on viruses – endorsed in March 2026

Ongoing

- GD on AMR
- GD “explanatory notes on data requirements on MO”
- GD on metabolites of concern
- Commission Communications (list of test methods/GD)

Planned (2026)

- Consensus document on MO and sensitising potential of MO

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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 for 27 substances** and linked to the agreement of guidance:
  - The Commission wrote to concerned applicants (+ RMS/co-RMS) to remind that the deadline for submission is **20 March 2026**
  - If not able to submit the whole package, at least: studies conducted and on-going and proposed action plan to finalise the submission

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GD on water treatment processes - Delays in the submission of confirmatory information

Out of the **27 active substances**, by 20 March 2026 (deadline for submission of the CI):

- For **8** (Pendimethalin, Mefentrifluconazole, Cypermethrin, Iodosulfuron, Flazasulfuron, Zoxamide, Foramsulfuron and Pyriproxyfen), the **whole package of confirmatory information was submitted → assessment of the RMS can start.**
- For **19** (Benzovindiflupyr, Propyzamide, Flupyradifurone, Cyantraniliprole, Isofetamid, Fenpicoxamid, Flutianil, Mesotrione, Mesosulfuron, Propoxycarbazone, Silthiofam, Trifloxystrobin, Carfentrazone-ethyl, Pethoxamid, Isoxaflutole, Carvone, Dimethenamid-P, Cyazofamid and Clopyralid) **only partial data package was submitted - extension requested → Commission is preparing a mandate to EFSA** to justify the extensions based on applicants' plans and study types (not full evaluation)
- For **8** (Benzovindiflupyr, Pendimethalin, Propyzamide, Flupyradifurone, Cyantraniliprole, Isofetamid, Fenpicoxamid and Cypermethrin) there will be an **overlap between CI and renewal assessments** – duplication and delays in the **submission of the RAR to be avoided**. Case by case.
- Communication with RMS/applicants via ScoPAFF/PAI/letters/emails

Update GD on birds and mammals

- Revised guidance for **birds and mammals** applicable for applications for a.s. and PPPs submitted from 1 October 2025.
- PAI agreed an approach for PPPs in September 2025 – 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.
- Further discussion in PAI (March 2026) – see minutes from that meeting

GD currently under preparation/revision or discussion in PAFF

Under preparation/revision:

- Updated guidance on emergency authorisations – technical guidance plus a Notice setting out scope following the Court ruling
- Negligible exposure – procedure to adopt the agreed draft will be initiated soon.
- Non target arthropods, soil organisms, non-target plants (+ Indirect effects on biodiversity)
- OPEX GD (closed transfer systems)
- Guidance for assessment of cross-resistance in Aspergillus spp. from use of PPP/BP (follow-up to azole mandate) – *mandate under preparation*

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 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.
- Currently **on-going** process to decide on the temporal percentile put forward by COM, liaising with EFSA (see next slide)

SW FOCUS scenarios – choice of the temporal percentile

- Process to decide on the temporal percentile put forward by COM, liaising with EFSA:
  - **January 2026:** technical info session chaired by EFSA for risk assessors and risk managers of MS. Stakeholders were invited.
  - **March 2026:** MS shared their preliminary positions: 80% (7 MS) , 90% (11 MS) and no position (3 MS) + impact assessment of CLE + testing report published.
  - **April/May 2026:** exchange with CLE to get the background data of the impact assessment and with EFSA to assess the content of these reports.
  - **PAFF June 2026:** *possible* endorsement of one of the percentiles by risk managers.
  - EFSA will implement the value in the models and use them

EU Pesticide Database Data Cleaning

The Database today

Currently includes approved, pending, non-approved, and substances not yet assessed at the EU level.

The Issue

The database contains 1,466 substances, many of which are *maybe* no longer relevant to the public or current regulatory needs, and the categorisation of the substances can be misleading

The Necessity

A thorough "cleaning" of the data is required so that statistics and "categorisation" accurately reflect the substances AS in use today.
The focus in on the currently "tagged" **NON APPROVED SUBSTANCES**

Criteria adopted

'Non Approved' substances remain public (probably "the tag will be renamed or newly tagged) if they have active regulatory links, such as:

- Specific non-approval before **Regulation 1107/2009**
- Established **MRLs**.
- Links to international safety and trade standards (**CODEX**)
- Emergency authorisation

Findings and proposed action

The Commissoin identified **145 active substances** that do not meet any of these criteria, and proposes to remove them from the EU Pesticide Database

Member States comments

Member States (Legislation PAFF) reviewed the list of 145 substances and provided input.
A further investigation is planned in May 2026 (Residue PAFF)

Website Revamp Strategy

Objective

Redesign our web presence to align with today's situation and topics, ensuring a strictly **facts-based** approach.

Targeted Communication

Provide different levels of information tailored to diverse audiences, ranging from **non-experts to experts**.

Visual Impact

Shift towards a more visual style to explain key concepts and complex regulatory data more effectively with the help of infographics. (e.g. inclusion of the EFSA's regulatory scrollers)

Dynamic Updates

Ensure the platform stays up-to-date on fast-moving topics and rapidly evolving scientific facts. Inclusion of milestones.

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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 26 the renewal process is on-going and for four the renewal process will start in the future – EFSA Conclusions are available for 4 (the remainder are with RMS or in peer review. Delays must be avoided)

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 carried out. DL for output: 31 July 2026. The Commission has also sent a second mandate to both EFSA and ECHA, focused on the **formation of TFA in soil and water.** DL for output: 1 June 2027.
- 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.

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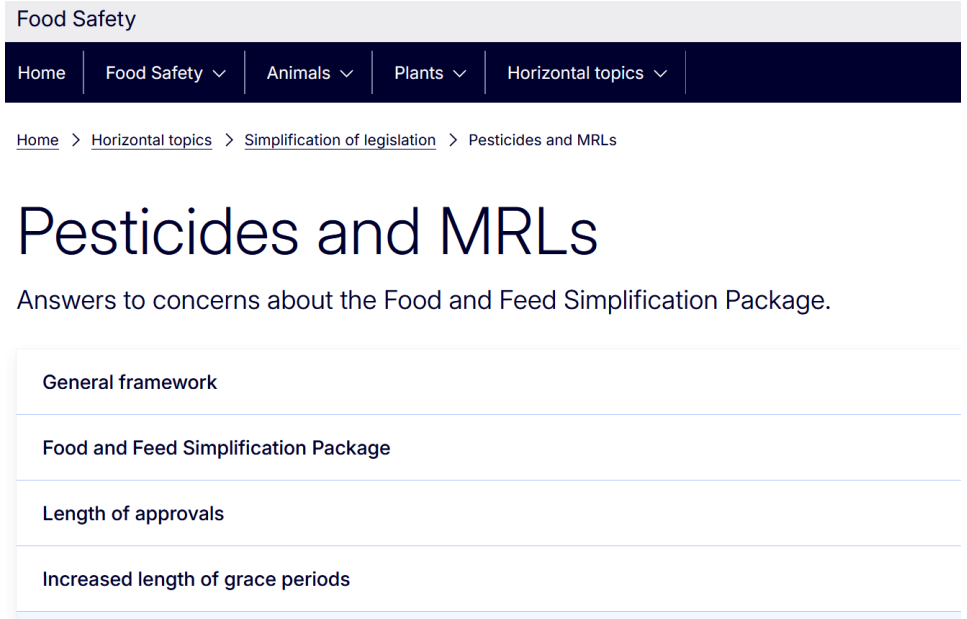
Food and Feed Simplification Package

On 16 December 2025, the Commission adopted a proposed package of measures to streamline and simplify EU food and feed safety legislation.

The Food and Feed Safety Package is a key deliverable from the Vision for Agriculture and Food presented by the Commission in February 2025, and directly responds to its promise of helping farmers and food and feed businesses be more competitive and resilient.

Further information including a Q&A document and answers to concerns are available online.



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

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Food and Feed Simplification Package

Organised in 3 proposals:

1. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending **Regulation (EU) No 528/2012** as regards the **extension of certain data protection periods**
2. Proposal for a DIRECTIVE OF THE EUROPEANPARLIAMENT AND OF THE COUNCIL amending Council **Directive 98/58/EC** and **Directive 2009/128/EC** of the European Parliament and of the Council as regards the **simplification and strengthening of food and feed safety requirements**, and repealing Council Directives 82/711/EEC and 85/572/EEC
3. Proposal for a REGULATION OF THE EUROPEANPARLIAMENT AND OF THE COUNCIL amending **Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC)No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625** as regards the **simplification and strengthening of food and feed safety requirements**

State of play: Discussions ongoing in the Council since January 2026, EP to start soon

Food and Feed Simplification Package: Regulation (EC) No 1107/2009

Biocontrol:

- Clear definition of biocontrol substances
- Member States must give priority to the assessment of applications for approval of new biocontrol active substances & authorisation of products containing them
- Possibility for Member States to grant provisional product authorisations while approval procedures for new biocontrol substances are still ongoing.
- One zone for product authorisations and reinforced zonal and mutual recognition (tacit agreement if 120-day deadline is not met)
- EFSA can take the role of rapporteur Member State for initial risk assessment (need for extra resources)
- Waiving of the record-keeping obligations for farmers for biocontrol products

Food and Feed Simplification Package: Regulation (EC) No 1107/2009

- Possibility for unlimited approvals for active substances with exceptions:
  - candidates for substitution (substances with problematic hazard properties)
  - substances approved under the derogation possibility set out in Article 4(7)
  - active substances for which a limited period of renewal is set in the light of relevant uncertainties emerging from the risk assessment including as a result of data gaps
  - transition measure: ongoing renewal procedures (~200) will continue
- Safeguards to maintain high level of protection:
  - Product authorisations remain limited (maximum 15 years) and subject to review and renewal
  - Obligation for Commission and Member States to periodically select substances with unlimited approval periods for full renewal or targeted reassessment (new provision – also applicable to substances with limited approval periods) – Possibility for review at any time (Art.21) and emergency measures (Art. 69) maintained.

Food and Feed Simplification Package: Regulation (EC) No 1107/2009

- Article 4(7) derogation allows approval for 5 years of active substances not meeting all approval criteria if they are necessary to control a serious danger to plant health or plant production – substances with the most severe hazards are excluded from this possibility. The obligation for Member States to submit a phasing out plan is removed.
- Longer grace periods when no reasonable alternatives are available – max of 3 years instead of 18 months
- Plus more……simplification for applications for extensions of authorisations to minor uses, restoration of EU-wide data protection periods (instead of 'per Member State'),
- Clarification related to:
- - "current scientific and technical knowledge" for product authorisation assessments
- - provisions for basic substances (including for product marketing and possibility for dual approval of basic/active substances) – currently Member States apply divergent rules.

  - provisions related to seeds treated with plant protection products, which Member States do not apply in a harmonised way.

Food and Feed Simplification Package: Regulation (EC) No 396/2005

- Possibility for implementation on a case-by-case basis of the principle announced in the Vision for Agriculture and Food that the most hazardous pesticides banned in the EU for health and environmental reasons will not be allowed back to the EU through imported products, if considered justified after an impact assessment

- Since the term “import tolerance” is often misunderstood, it is replaced for clarity by "MRL based on a good agricultural practice in a third country".

- Allow for transitional measures in all cases where MRLs are lowered

- Allow the setting of permanent (instead of temporary) MRLs based on monitoring data

- Align the terminology of the technical zero by applying the term limit of quantification (LOQ).

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Take home message from RM to peer reviewers

- Alternative PPPs are needed for the farmers toolbox: please give priority to new active substances, wherever possible
- 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),
  - **Consistency and coherence** is critical: within the same substance and between different substances.,
  - consider RMM and lower range of GAP to see if there is a safe use = **ONE SAFE USE PRINCIPLE**
- **Need to avoid delays!** *N.B.* Cases T-412/22, T-94/23 and T-565/23

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Thank you for your attention

For further information:

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

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