



10th PSN-IUCLID

Latest news from the European Commission

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EU assessment of co-formulants in PPPs

The Blaise judgement (C-616/17) states that the assessment of a PPP must be undertaken as part of the EU assessment and that therefore, all aspects of the product needs to be examined and safety demonstrated.

When:

1. Evaluating co-formulants in the **product(s) for representative use (at EU level for approval of AS)** and
2. Evaluating co-formulants in the **product(s) for authorization (at MSs level)**

Progress on co-formulants in PPPs:

3 objectives:

1. To develop a guidance to harmonise the assessment of PPPs;
2. To establish an EU database of co-formulants (need for sharing data and assessments of co-formulants and products in view of ensuring efficient use of resources);
3. To improve a clear communication on the legal framework and on ongoing activities.



actions

- updates on website: [The Assessment of Plant Protection Products \(PPPs\) \(europa.eu\)](https://europa.eu)
- continuous discussions on the database and guidance (ScoPAFF, PAI, ZAPID workshop)
- Regulation 383/2021: 11 notifications received so far for additional unacceptable substances to be listed in Annex III (carc cat 1, PBT/vPvB, POP, or no more BPR). Amendment of Annex III will be initiated.
- Art 27 (3) applies for unacceptable coformulants which are already on the market.

Possible information to be addressed in the content of the database (possibly using IUCLID)

- Trade name(s) and detailed composition of the co-formulant(s) -substances or mixture
- IUPAC name; Identifiers (e.g. CAS/EC No, InChI (-key), REACH Reg. N. SMILES, UFI, etc.)
- % w/w , purity, impurities
- Type -according to REACH (mono-constituent, multi-constituent and UVCB), Function, Manufacturers
- List of PPPs in which the co-formulant (substances or mixtures) can be found
- Info on classification for the co- formulant / each substance of mixtures
- Eco and toxicological endpoints and existing risk assessment if any.
- Additional data in case of specific co-formulants (co-formulants that are approved/no more approved/not approved as pesticide a.s, co-formulants that are polymers, co-formulants that are UVCBs, co-formulants that are PFAS) and co-formulants that are formaldehyde releasers.
- Equivalent co-formulants (according to SANCO/12638/2011)

'One Substance, one Assessment package

- Ongoing negotiations in the European Parliament and in the Council on the Commission proposals under the 'One Substance, one Assessment package.
- It includes proposals for a regulation establishing common data platform on chemicals, for a directive amending the Directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment as regards the reattribution of tasks and for a regulation on the reattribution of tasks.
- Upcoming Coreper discussions on 14 June that will aim to agree on a Council's negotiating position.
- Indicative EiF

Commission Regulation on Safeners and Synergists

- Recently published, 29 May 2024: <https://eur-lex.europa.eu/eli/reg/2024/1487/oj>
- Entry into force 19 June 2024

Scope:

- Setting data requirements (Art 25) – similar to the ones for active substances plus Annex III (Efficacy data).
- Establishing the work programme for a gradual review of the S&S (Art 26)

Dates to keep in mind:

- By 19 July 2024: **publication the non-exhaustive list** of substances currently used as S&S in PPPs.
- By 19 December 2024: **any interested party may submit a notification of further substances or preparations used as S&S** in plant protection products authorised for the placing on the market in at least one Member State.
- By 19 June 2025: **Any interested party wishing to submit an application**, in accordance with Article 7 of Regulation (EC) No 1107/2009, **for the approval of a safener or synergist**, may submit a request for inclusion of that safener or synergist in the work programme for gradual review.
- 19 December 2025, **adoption of the work programme. For the substances included on it:**
 - By 19 June 2028 (48 months after entering into force): **applications for the approval of a safener or a synergist shall be submitted (in IUCLID format).**
 - until five years of the adoption of the work programme, **transitional period** for products already on the market that contain these substances.