



A PAN Europe contribution to the European Commission's public consultation on the assessment of **Safeners and Synergists**

"Plant protection products – data requirements and gradual review of safeners and synergists."

The Pesticide Network Europe (PAN Europe) welcomes the European Commission's long overdue (9 years) draft Regulation defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists in the EU market. This is crucial to eliminate the discrepancies in methodologies and level of protection that exist between Member States when assessing safeners and synergists. PAN Europe finds the European Commission's draft Regulation satisfactory in terms of setting data requirements at the same high level as for active substances, given their equal application onto our food and the environment.

However, the proposed draft Regulation has certain limitations **that must be addressed to ensure its full compliance with the provisions of the EU Regulation on Pesticides**. These are the following :

1. **Additional lengthy delays in the regulation of safeners and synergists:** the proposed timeline for the work programme for the gradual review of safeners and synergists currently on the market is excessively lengthy: 6.5 years. The Commission has to adopt the work programme in 18 months from the date of entry into force of the text. Safeners and synergists are expected to be reviewed within five years of the adoption of the work programme. The timeline foreseen is unacceptably long, and the ground of justification is simply insufficient. The draft Regulation specifies that the length of the procedure for review is "*To ensure alignment with the derogation provided for in Article 81(1) of Regulation (EU) No 1107/2009*". This article provides that a Member State may authorise, in the 5 years following the adoption of the programme referred to in Article 26, a pesticide product containing safeners and synergists, which have not been approved, where they are included in that programme (Art.81(1)). However, Article 26 specifies that the work programme should have been adopted by 14 December 2014 and therefore, the complete review of safeners and synergists should have already been

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completed, had this article been respected. Provided that the final Regulation on safeners and synergists would be adopted next year, this would mean that their review would not be complete before 6.5 years, which could bring us to 2031. This is particularly concerning given that the safeners and synergists currently authorised in the EU are being evaluated on the basis of different data requirements and authorised on different criteria between Member States, and therefore their toxic properties could be largely unknown. The complete review period should be shortened to a maximum of 3 years.

2. **No food residue safety limits for safeners and synergists:** For the data requirements, the draft Regulation includes the identification and proposal of a residue definition for safeners and synergists, where relevant (Art.9(1) §c). However, the draft Regulation does not foresee setting Maximum Residue Levels (MRLs) in food. It is important to note that the MRL Regulation states that the cumulative and synergistic effects of the active substance with other pesticide residues should be taken into account¹. Article 4(2) of the EU Regulation on Pesticides provides that the residues of the plant protection products should not have any harmful effects on human health or animal health. Although this applies to all the substances that the product consists of, to date, only active substances in food are thoroughly assessed and regulated, and not safeners, synergists and co-formulants. A reference to set MRLs for safeners and synergists should be included in the legal text.
3. **Authorisation of products containing unregistered safeners and synergists or without a valid application should be immediately withdrawn:** The draft Regulation foresees establishing a list of all of the safeners and synergists already on the market in EU Member States. On the basis of this list, any interested party wishing to submit an application for the approval of a safener or synergist may submit a request for its inclusion in the work programme for gradual review. The draft Regulation provides that where no request for inclusion in the work programme for gradual review is received for a listed safener or synergist within the specified deadline (Article 4(1)), the Commission will adopt a decision stating that the respective safener or synergist is not included in the work programme. In this case, pesticide products containing a safener or synergists with no application would remain on the market for an additional 5 years after the adoption of the work programme. This would also be the case for the safeners and synergists whose applications are deemed inadmissible due to non-compliance with the data requirements. This is unacceptable and contradicts the provisions of the EU Regulation on Pesticides aiming to ensure that products and their ingredients cause no harmful effects to humans, animal health and the environment. The authorisations of the plant

¹ Regulation (EC) 396/2005

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protection product containing safeners and synergists for which no application has been submitted or whose application has been deemed inadmissible should be withdrawn at national level when the work programme is adopted.

- 4. Strengthening the reference to the protection of human health and the environment:** Finally, although the draft Regulation refers to Article 4 of Regulation (EC) 1107/2009, it is important to specify that the general provisions of Article 1 are applicable. These provisions aim to ensure a high level of protection for human and animal health as well as the environment, are underpinned by the precautionary principle and extend to both safeners and synergists.

Contact: PAN Europe, Lysiane Copin, lysiane@pan-europe.info and/or Angeliki Lyssimachou, angeliki@pan-europe.info

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