

**Question for written answer E-003066/2024
to the Commission**
Rule 144
Christophe Clergeau (S&D)

Subject: Re-approval of 8-hydroxyquinoline and use of the negligible exposure criterion

During the meeting of the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) of October 2024, Member States discussed the Commission's proposal to re-approve 8-hydroxyquinoline. 8-hydroxyquinoline is classified as toxic for reproduction category 1B (reprotox 1B), therefore meeting a so-called 'cut-off criterion' under Regulation (EC) No 1107/2009¹. Harmful substances classified as toxic for reproduction category 1B in accordance with point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 can therefore only be approved if it is demonstrated that exposure to humans is negligible. The Commission proposes to re-approve 8-hydroxyquinoline for use in drip irrigation in permanent greenhouses, as it considers the negligible exposure criterion to be fulfilled. It would be the first time this criterion has been deemed fulfilled.

Considering the above, can the Commission justify its intention to re-approve a 'cut-off' substance:

1. on the basis of a guidance document on the assessment of negligible exposure that has not been adopted by the Member States and which raised severe concerns already in 2014, as the use of the negligible exposure criterion could be seen as a way to derogate from the hazard-based procedure, by introducing a more risk-based one?
2. in the light of EFSA's finding² that 'the available field study was concluded as not reliable and did not allow an ad hoc approach for the non-dietary exposure assessments', and that it asked for 'a more reliable and realistic assessment of the non-dietary exposure' to be submitted?
3. where the assessment of non-dietary exposure of bystanders and resident children cannot be concluded since the predicted exposure estimates with the European Food Safety Authority (EFSA) model are very likely to be overestimated?

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¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

² <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2024.8670>.