

(English version)

**Question for written answer E-003066/24
to the Commission
Christophe Clergeau (S&D)
(19 December 2024)**

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 cB (reprotox 1B), therefore meeting a so-called 'cut-off criterion' under Regulation (EC) No 1107/2009⁽¹⁾. Harmful substances classified as toxic for reproduction Category cB 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 finding⁽²⁾ 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?

Submitted: 19.12.2024

**Answer given by Mr Várhelyi on behalf of the European Commission
(24 February 2025)**

The re-approval of a substance classified as toxic for reproduction Category cB is possible when exposure to humans under realistic conditions of use is considered negligible.

The discussions at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) were based on the findings regarding exposure in the recent scientific assessment carried out by the European Food Safety Authority (EFSA).

Dietary exposure is considered negligible as EFSA found that the residue levels are below the default value as set out in point 3.6.4 of Annex II to Regulation (EC) No 1107/2009⁽¹⁾.

For non-dietary exposure, the discussions in SCoPAFF focused on strict conditions to ensure that exposure is reduced to a level considered negligible.

The proposed conditions include a use restriction in permanent greenhouses via a closed transfer system designed to avoid the exposure of operators during mixing and loading for application via drip irrigation.

Although the study referred to by the Honourable Member had certain limitations, the data available suggest that exposure via air is unlikely⁽²⁾.

To increase confidence in this conclusion, the proposed approval conditions include a requirement to submit a new study on non-dietary exposure as confirmatory information.

EFSA considered the predicted exposure of bystanders and residents to be an overestimate; This is because the estimates in the EFSA conclusion were based on data from application by spraying, while the actual representative use is via drip irrigation in permanent greenhouses.

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>.

⁽¹⁾ <http://data.europa.eu/eli/reg/2009/1107/oj>

⁽²⁾ The study monitored the concentrations in air inside and outside the greenhouse and no peaks were found in any of the samples. The lack of detection peaks shows that exposure via air is unlikely and can be considered negligible.

Therefore, the resulting exposure will be significantly lower ⁽³⁾. EFSA also concluded that exposure via volatilisation is low ⁽⁴⁾.

⁽³⁾ As also reported in the EFSA conclusion, for example on page 27 ‘Predicted exposure to vapour is exceeding the (A)AOEL for children, but these values are very likely overestimated due to the model assumptions as it is based on data for spray application and not for drip irrigation. (RMS suggested that the product should only be applied in high-technology greenhouses, preventing the exchange of vapours of the active substance with the outside. During the peer review meeting, the experts agreed that this should be considered at Member State level for national authorisations)’.

⁽⁴⁾ See page 9 of the EFSA conclusion ‘This was considered possible for the drip irrigation use because the substance Henry’s Law constant is below 1 Pa m³ mol⁻¹; this indicates active substance volatilisation would be low, so minimising the possibility for its condensation on greenhouse structures’.