

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance orange oil<sup>1</sup>

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#### ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State France, for the pesticide active substance orange oil are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative use as an insecticide for the control of whitefly larvae and adults on tomato and courgette (field, glasshouse, indoor). The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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#### KEY WORDS

Orange oil, peer review, risk assessment, pesticide, insecticide

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## SUMMARY

Orange oil is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC France (hereinafter referred to as the 'RMS') received an application from Oro Agri for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2009/438/EC.

The RMS provided its initial evaluation of the dossier on orange oil in the Draft Assessment Report (DAR), which was received by the EFSA on 12 August 2009. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received on 10 February 2012. The peer review was initiated on 27 February 2012 by dispatching the DAR for consultation of the Member States and the applicant Oro Agri.

Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should adopt a conclusion on whether orange oil can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of orange oil as an insecticide on tomato and courgette as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified for the section identity, physical and chemical properties and analytical methods.

In the mammalian toxicology section, due to the lack of either toxicological studies to allow an independent assessment of the toxicity profile of orange oil, or data to allow the establishment of robust background exposure levels for European consumers through the diet, a possible surrogate background exposure from D-limonene used as a flavouring ingredient is compared to operator, worker and bystander exposure. Greenhouse applications were not addressed for operator exposure and the risk assessment could not be finalised for this scenario (data gap). The nature of the residues to which workers are exposed was not addressed and worker exposure risk assessment could not be finalised. The relevance of compounds present in the technical material has not been addressed and a data gap was identified.

A final conclusion on the dietary risk for consumers with regard to pesticide residues is currently not possible since the nature of the pertinent residue on the treated crops has not been confirmed as D-limonene.

A data gap has been identified to address the fate and behaviour of limonene in soil including photolysis in soil study already on going. Batch soil adsorption/desorption studies or a reliable estimation of the K<sub>oc</sub> of D-limonene and its soil metabolites needs to be provided. A data gap for reliable information on the fate and behaviour of D-limonene in aquatic systems (including water and sediment) is identified. A justification on the fate of the other components would be needed. A number of scientific papers are quoted in the DAR that are not available in the dossier. These papers would need to be submitted and assessed in order to be taken into consideration in the EU assessment. Consistent with the assessment performed for R-carvone, the default worst case degradation parameters assumed in the absence of experimental data and QSAR K<sub>oc</sub> should be considered, applying appropriate uncertainty factors. PEC<sub>SW</sub> have been calculated using the EVA 2.0 tool. The surface water environmental risk assessment of limonene soil and water metabolites will need to be revisited once the data gaps on the degradation in soil and aquatic systems are fulfilled. PEC<sub>GW</sub> for limonene and its soil metabolites need to be provided.

Data gaps were identified in the ecotoxicological section to further consider: 1) the risk to birds and mammals, including secondary poisoning; 2) the risk to aquatic organisms, including the chronic risk assessment for aquatic organisms and the potential for bioaccumulation. These data gaps were identified because the endpoints from the WHO publication could not be confirmed due to the lack of the original reports.