

**Point 4.b**

**Dossier Chlorothalonil**

The expiry date for the approval of chlorothalonil as active substance in plant protection products has been extended until 31 October 2018 in order to allow for the renewal procedure to be finalised.

On 30 January 2018 the EFSA published its conclusions on the peer review of the pesticide risk assessment of the active substance chlorothalonil. These conclusion are available online via the following link: <https://www.efsa.europa.eu/en/efsajournal/pub/5126>.

Based on the EFSA conclusion the approval criteria do not seem to be satisfied due to the following reasons:

- the outcome of the groundwater risk assessment is negative as 9 relevant metabolites were identified in groundwater at concentrations exceeding 0.75 µg/L for all FOCUS scenarios for every representative use evaluated.
- the outcome of the consumer risk assessment is negative as a genotoxicity concern cannot be excluded for residues to which consumers will be exposed. Furthermore the residue definitions for risk assessment in plant and animal commodities are preliminary. In the absence of toxicological reference values for the metabolite R182281, even an indicative consumer risk assessment using the preliminary residue definitions cannot be conducted.
- the outcome of the ecotoxicological risk assessment is negative as a high acute and chronic risk to amphibians was concluded as well as a chronic risk to fish.
- The risk assessment to unique human metabolites could not be finalised due to lack of data.

- The analytical methods used in the toxicological studies were not identified and therefore not validated, which questions the validity of the studies, in particular repeated-dose dietary studies

Based on the issues discussed above, no safe representative use could be identified. The Commission has therefore proposed a non-renewal of approval for chlorothalonil. The proposal includes a grace period of maximum 15 months from the date of entry into force of the adopted proposal. The proposal is currently under discussion with the Member States. After the inter-service consultation in the Commission, the draft Regulation will be notified to the WTO under the TBT procedure to give 3<sup>rd</sup> countries the possibility to comment. Thereafter the draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance chlorothalonil will be presented to the Standing Committee Plants, Animals, Food and Feed for an opinion. Exact timing is not yet known.