

Dutch response on the Scientific opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid (EFSA Journal 2013;11(12): 3471).

The Netherlands can agree with the fact that the DNT studies available for acetamiprid and imidacloprid both have their deficiencies.

For acetamiprid no DNT study was available in the EU dossier, the US-EPA DNT study was not available for review for the member states. In the opinion EFSA takes into account an effect which was not taken into account by the US-EPA and JMPR (it is noted that the evaluation of this study by JMPR (2011) was not taken into consideration by EFSA). EFSA did not report the details of the effect. These details are necessary to consider the effect as adverse (no information about the significance, standard deviation, and historical control information).

For imidacloprid EFSA, in contrast with its previous evaluation of this compound, proposes to use a very conservative method to estimate the "NOAEL". The Netherlands is of the opinion that the additional safety factor of 10 is very conservative (usually the factor to derive a NOAEL from a LOAEL is 3, however other values were also used previously). The opinion did not explain why a factor of 10 was chosen. Furthermore, also for imidacloprid no details about the effect are described in the opinion (no information about significance, historical control, etc). This information is crucial to consider a certain observation as an adverse effect.

The Netherlands proposes to re-consider the ADI, ARfD and AOEL of acetamiprid and imidacloprid during the renewal of the inclusion. The EFSA opinion is a good starting point for the notifier to reconsider the DNT studies and address the deficiencies which are pointed out in the opinion.