Innspill til EFSA GMO Extranet

Søknad EFSA/GMO/NL/2012/109 - Oilseed rape 73496

D.07.08

Toxicology

A general comment to the toxicological study available is that it is too old and not according to OECD guidelines. New toxicological studies according to OECD guidelines should have been performed.

The Norwegian Panel on Genetically Modified Organisms points out that the acute toxicity study has not been performed according to OECD guidelines 420. The exposure should have been performed with a high enough toxic concentration and a proper length of observation period. The acute study should also have been performed with a fixed dose of 2000 mg test substance/kg bw. Moreover, a NOAEL is determined based on these acute studies of 8-9 days. According to the OECD guidelines it is not recommended to determine NOAEL based on acute oral toxicity studies. The acute study is designed for determination of LD_{50}. Moreover, a NOAEL should be determined based on the acute study Guideline No. 423.

The applicant has not performed a 90-day sub-chronic study according to OECD guidelines 408. The applicant should have included tests on relevant species that would have been a great help for the assessment of the rapeseed as food and feed substance. The Norwegian GMO Panel finds it difficult to conclude on this risk assessment due to the lack of information based on the available studies. The Norwegian GMO Panel requests the applicant to perform appropriate feeding studies according to the OECD guidelines