

Innspill til EFSA GMO Extranet

Søknad EFSA/GMO/NL/2009/75,

oljeraps MS8 x RF3 x GT73

A general comment to the toxicological studies available is that they are 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 studies were not performed according to OECD guidelines 420. The exposures should have been performed with a high enough toxic concentration and a proper length of observation period. The acute studies should also have been performed with a fixed dose of 2000 mg test substance/kg bw.

Although some animal studies have been performed on the parental events (MS8, RF3, GT73, and MS8 x RF3), the applicant should also have performed feeding studies (production animals included) with the triple stacked event MS8 x RF3 x GT73. In addition, these studies should be performed using rapeseed from both glyphosat and glufosinate-ammonium treated and untreated crops.

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.