

# Innspill til EFSA GMO Extranet

## Søknad EFSA/GMO/NL/2010/87 – MON 88302

The Norwegian Scientific Committee/Panel on Genetically Modified Organism (GMO Panel) has evaluated the MON 88302 as a food and feed ingredient.

### **Comments to the toxicological assessment of MON 88302:**

A general comment to the toxicological study available is that it is too old and not performed according to OECD guidelines. Updated literature or 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 was not 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 upto a toxic effect occurs or with a fixed dose of 2000 mg test substance/kg bw. Moreover, a NOAEL is determined based on this acute study of 8-9 days. According to the OECD guidelines it is not recommended to determine NOAEL based on acute oral toxicity studies since they are limited to a short observation period. The acute study is designed for determination of LD<sub>50</sub>. Moreover, a NOAEL should be determined based on the 90-day sub-chronic study according to OECD guidelines 408.

The applicant has not performed 90- day sub-chronic study according to OECD guidelines 408. This experiment should have been performed using oilseed rape exposed and unexposed to glyphosate for a proper assessment of the MON 88302 as food and feed ingredient(s).

The applicant should also have included feeding studies on relevant production animals normally fed on feed supplemented with feed ingredients from oilseed rape. Such studies would have been of great help for the assessment of MON 88302 as a food or feed ingredient. The Norwegian GMO Panel finds it difficult to conclude on this risk assessment due to lack of appropriate feeding studies. The Norwegian GMO Panel requests the applicant to perform appropriate feeding studies according to the OECD guidelines.