

Innspill til EFSA GMO Extranet søknad EFSA/GMO/NL/2011/93 - MON 87708

General comments

The GMO Panel of the Norwegian Scientific Committee for Food Safety has not found any analysis of the residues of the herbicide applied nor its metabolites as part of the compositional analysis. It is of importance to know the residues level, because the herbicide resistance provided by the genetic modification allows a more intensive use of the herbicide and it enables the plant to degrade the herbicide into metabolites which naturally would not occur in plants in the same concentrations. The metabolites, DCSA, DCGA and 5-OH-dicamba should also be analysed. We recommend that the applicant provides a description of all herbicides which may be used in the cultivation of MON87708 and their metabolites. Moreover an analysis of the soybean with regard to the herbicide applied and their metabolites is mandatory.

D.07.08

Toxicology

The GMO Panel of the Norwegian Scientific Committee for Food Safety has evaluated soya MON 87708 as a food and feed ingredient. The acute toxicity study is performed using 140 mg protein/kg bw. This is a very low amount according to the OECD guidelines (OECD guidelines 420). If the acute study is performed with a fixed dose the exposure limit is 2000 mg test substance/kg bw. Moreover, a NOAEL is determined based on this acute study. According to the OECD guidelines it is not recommended to determine NOAEL based on acute oral toxicity studies since they limited to a 14 days observation period. The acute study is designed for determination of LD50.

NOAEL should be determined based on the 90 days sub-chronic study (OECD 408).

All animal experiments are performed using soya unexposed to Dicamba. Herbicide treated soya should have been included in the animal experiments, and the residue level of the herbicide and its metabolites should have been analysed.

Fish meal and fish oil has to some extent been replaced by plant meal and plant oil. Soy meal and soy oil is today important ingredients in feed for marine fish. The Norwegian GMO Panel request that the applicant perform feeding studies on fish, e.g. salmonides.