

**Innspill til EFSA GMO Extranet**  
**Søknad EFSA/GMO/NL/2011/91**  
**General comments**

**D.07.08**

**Toxicology**

The Norwegian Panel on Genetically Modified Organism (GMO Panel) has evaluated the DAS-68416-4 as a food and feed ingredient.

All animal experiments are performed using soybean unexposed to 2,4-D and glufosinate. Herbicide treated soya should have been included in the animal experiments, and the residue level of the herbicides and their metabolites should have been analysed.

Fish meal and fish oil has to some extent been replaced by plant meal and plant oil in the aquaculture industry. 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, primarily in salmonides.

The Panel points out that the effects in males on feed intake, daily gain and feed efficiency in the broiler study should not be overlooked. Moreover, a NOEL is determined based on the acute study Guideline No. 423. According to the OECD guidelines it is recommended to determine NOAEL based on a 90 days sub-chronic study (OECD guidelines 408).

OECD Guideline for Testing of Chemicals; Guideline No. 423: Acute Oral Toxicity-Acute Toxic Class Method and OECD Guideline for Testing of Chemicals; Guideline No. 407: Repeated Dose 28-day Oral Toxicity-Study in Rodents; are not recommended for setting an NOEL since they are limited to 14 and 28 days observation period. The acute study is designed for determination of LD<sub>50</sub>.

The opinion of the GMO Panel is that 90 days sub-chronic study should have been conducted (OECD 408) because that study gives a longer observation period for detection of eventually toxic effects. The GMO Panel finds it difficult to conclude that soy meal is non-toxic since there are indications of effects on males from the 42 days broiler study.

Limited studies make it challenging to perform a complete risk assessment.