Innspill til EFSA GMO Extranet

Søknad EFSA/GMO/DE/2010/86–
Maishybrid Bt 11x MIR162 x 1507 x GA21

D.07.08 Toxicology

The Norwegian Panel on Genetically Modified Organism (GMO Panel) has evaluated the BT11x MIR162x1507x GA21 as a food and feed ingredient.

The applicant has performed acute testing separately for each Cry protein, PAT, mEPSPS, Vip3Aa20 and PMI proteins. The applicant has not performed acute studies using a combination of all transgenic proteins in order to detect possible combinatorial effects, being either additive or synergistic. Neither was a 90-days subchronic oral feeding study nor a 50 days broiler study conducted on the maize hybrid (according to OECD guideline 408). Both should have been performed on the maize hybrid treated with and without herbicide. Relevant feeding studies with the maize hybrid in domestic animals including farmed fish such as salmonids and mammals should also be performed.

The applicant has evaluated a NOEL from the acute study which is not recommended by the OECD guidelines. A NOAEL should be evaluated from the repeated dose 90-day oral toxicity study in rodents on whole food/feed (OECD guideline 408) (Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed**,** EFSA journal 2011 9(12):2438). The NOAEL from this study should be the basis for the calculation of the MOE and not the acute toxicity study.

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