Comments from The Norwegian Scientific Committee for Food Safety (VKM) GMO Panel on the application for event maize VCO-01981-5 (EFSA-GMO-DE-2016-130)

A, 4. Toxicological assessment

The applicant has performed a 14-day single dose toxicity study and argues that this test is sufficient and that a 28-day repeated dose toxicity study would not provide any additional value for the risk assessment. The VKM-GMO Panel does not agree with the argumentation that a 28-day repeated dose toxicity study can be replaced by a 14-day single dose acute toxicity study.

A, 5. Allergenicity

1) It should be clarified if all allergenicity discussed in the application is related to IgE or not.

2) The EFSA guidance document states that if the recipient plant for the modification is known to be allergenic, any known endogenous allergens should be tested for any change in allergenic potential. The applicant has assessed the LTP protein in maize VCO-Ø1981-5, but did not provide any justification for omitting assessment of the other allergen, the 16-kDa trypsin inhibitor.