

Comments from The Norwegian Scientific Committee for Food safety (VKM) GMO Panel on the application for stacked event maize 1507 x MON810 x MIR162 x NK603 (EFSA-GMO-NL-2015-127)

Maize stacked event 1507 x MON810 x MIR162 x NK603 confers herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively, and protection against lepidopteran target pests based on the presence of the insecticidal Cry1F, Cry1Ab and Vip3Aa20 proteins, conferring independent modes of action for insect protection.

Comparative assessments

A, 3.3. For compositional analysis: Based on the scientific information and tables given by the applicant for parameters required in OECD and EFSA guidelines using the analytical methods described, the VKM GMO Panel has the opinion that 1507xMON810xMIR162xNK603 maize grain and forage are compositionally similar to those of its conventional counterpart, and/or other conventional maize varieties.

A, 3.5. For effect of processing: The conclusions drawn by the applicant that “there are no metabolic pathways affected or new metabolites produced in 1507xMON810xMIR162xNK603 maize” are not supported by the parameters provided using the targeted analyses described. Untargeted assays such as transcriptomics, proteomics and/or metabolomics are needed to support such statements. Although OECD and EFSA guidelines at present do not require such analyses, the conclusions, as they are currently worded, are misleading and the applicant should consider rephrasing or removing them.

Furthermore, maize gluten meal (MGM) is a commonly used protein-rich ingredient in feeds for companion animals and fish. Processing steps to produce MGM are quite mild and the newly expressed proteins, such as Cry1F, Cry1Ab and Vip3Aa20, will possibly be present in MGM at considerably higher concentrations than in unprocessed maize. Especially Vip3Aa20 is present at relatively high levels in unprocessed maize grain (mg per kg level) and the Norwegian VKM's GMO panel considers that documentation regarding levels expected in MGM would be of value for considerations regarding hazard identification for untested non-target animals such as dogs and cats, as well as salmon, trout and other carnivorous farmed fish species.

Food and feed safety assessment

A, 4. For toxicological assessment: Based on data provided by the applicant, the GMO panel is of the opinion that sufficient data are provided on the toxicological properties of the newly expressed proteins. No hazard indicating toxicity has been identified in any of the single event maize lines. However, information on synergistic/antagonistic interactions between the proteins in non-target organisms is lacking, especially at higher levels presumably present in processed maize products such as MGM (see above).

A, 5. For allergenicity and adjuvanticity: The applicant claims that insecticidal-proteins have not been identified as allergens or adjuvants. However, various studies indicate that effects due to Cry1Ac's adjuvant properties cannot be ruled out. Relevant levels of the insecticidal Bt proteins in processed maize products such as MGM (see above) should also be taken into consideration for allergenicity and adjuvanticity development in untested non-target animals.

A, 6. For nutritional assessment: Data provided did not reveal performance differences between feeding groups in the broiler study conducted with maize 1507xMON810xMIR162xNK603 and its conventional counterpart and other commercial maize varieties. However, The VKM GMO panel is of the opinion that data on residues levels of the intended herbicides glyphosate and glufosinate should have been provided.