FG3s innspill til EFSAnet for søknad EFSA/GMO/DE/2009/67

D, 03

For stacked events, The Norwegian Scientific Committee for Food Safety would like to remind the applicant that EFSA requests a risk assessment on the potential for any interactions between the stacked events which could impact on human or animal health and/or the environment.

D, 07.02

According to the EFSA Guidance Document for the risk assessment of GM plants, it is advisable that experiments with herbicide tolerant crops "include both blocks of genetically modified plants exposed to the intended herbicide and blocks not exposed to the herbicide". In the study report on the compositional analyses it is not indicated whether the experimental design also included Bt11 x MIR162 x GA21 maize blocks not treated with herbicides containing glyphosate and glufosinate-ammonium. The applicant is asked to clarify whether the field trials for comparative assessment include blocks of Bt11 x MIR162 x GA21 not exposed to the intended herbicides(s), and to include compositional data from Bt11 x MIR162 x GA21 maize treated and not treated with the herbicide(s).

D, 07.09 Allergenicity

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Scientific studies, also very recent ones, have shown that the Cry1Ac protein is a potent systemic and mucosal adjuvant, which is an enhancer of immune responses. The GMO Panel of the Norwegian Scientific Committee for Food Safety find it difficult, based on the available data, to assess whether kernels from maize Bt11x MIR162 x GA21 may cause more allergenic reactions than food and feed from unmodified kernels. As the different Cry proteins are closely related, and in view of the experimental studies in mice, the GMO Panel finds that the likelihood of an increase in allergenic activity due to Cry1Ab proteins in food and feed from maize Bt11x MIR162 x GA21 cannot be excluded. Thus, the Panel's view is that as the adjuvant effect of Cry1Ab with reasonable certainty cannot be excluded, the applicant in relation to a possible adjuvant effect of Cry1Ab must comment upon the mouse studies showing humoral antibody response of Cry1A proteins. Further, although Cry1Ab proteins is rapidly degraded in gastric fluid after oral uptake, there is also the possibility that the protein can enter the respiratory tract after exposure to e.g. mill dust. Finally, rapid degradation is no absolute guarantee against allergenicity or adjuvanticity.

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