D, 05: Stacked events: The applicant is asked to test the maize for genetic stability of the inserts for more than one generation, e.g. three growing season and multiple locations representing different environmental conditions.

D, 07.01: The expression of the cry1A.105 gene in MON 89034 x 1507 x MON 88017 x 59122 is about 100 % higher in pollen and about 50 % higher in corn compared to MON 89034. The applicant is asked to explain these differences.

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 MON 89034 x 1507 x MON 88017 x 59122 maize plots were treated with glyphosate/glufosinate. The applicant is asked to clarify whether treatments with glyphosate/glufosinate were performed, and to include compositional data from MON 89034 x 1507 x MON 88017 x 59122 maize treated and not treated with glyphosate/glufosinate.

7.9 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 MON 89034 x 1507 x MON 88017 x 59122 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 Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins in food and feed from maize MON 89034 x 1507 x MON 88017 x 59122 cannot be excluded. Thus, the Panel's view is that as the adjuvant effect of Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1 and Cry35Ab1 with reasonable certainty cannot be excluded, the applicant in relation to a possible adjuvant effect of Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1 and Cry35Ab1 must comment upon the mouse studies showing humoral antibody response of Cry1A proteins. Further, although Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1 and Cry35Ab1 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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