

FG3s innspill til EFSA-net til søknad EFSA/GMO/NL/2009/65

D.03

For stacked events, according to the guidance document from EFSA applicants are requested to carry out 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. The Norwegian Scientific Committee for Food Safety asks the applicant to assess the impact of the difference in the expression levels of Cry1A.105 in pollen and seed when comparing MON 89034 with the stacked hybrid MON 89034 x 1507 x NK603.

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 MON 89034 x 1507 x NK603 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 MON 89034 x 1507 x NK603 not exposed to the intended herbicide(s), and to include compositional data from MON 89034 x 1507 x NK603 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 MON 89034 x 1507 x NK603 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 and Cry2Ab2 proteins in food and feed from maize MON 89034 x 1507 x NK603 cannot be excluded. Thus, the Panel's view is that as the adjuvant effect of Cry1A.105, Cry1F and Cry2Ab2 with reasonable certainty cannot be excluded, the applicant in relation to a possible adjuvant effect of Cry1A.105, Cry1F and Cry2Ab2 must comment upon the mouse studies showing humoral antibody response of Cry1A proteins. Further, although Cry1A.105, Cry1F and Cry2Ab2 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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Rojas-Hernández S, Rodríguez-Monroy MA, López-Revilla R, Reséndiz-Albor AA, Moreno-Fierros L., 2004. Intranasal coadministration of the Cry1Ac protoxin with amoebal lysates increases protection against *Naegleria fowleri* meningoencephalitis. *Infect Immun.*, 72:4368-4375

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