Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Innspill til EFSAnet 22/09-07

Pioneer Hi-Bred's maize 59122 x NK603
EFSA/GMO/UK/2005/20

COMMENTS OR OBJECTIONS TO THE PLACING ON THE MARKET OF A GMO UNDER REGULATION 1829/2003

D 2
According to figures 5, 6, 7, and 8 the observed band size in lane 11 (sample 59122xNK603-T14) and 12 (sample 59122xNK603-T15) differ about 100-150 bp. Explain the difference. According to figure 5 the observed band size in lane 5 (59122-T1) and lane 6(59122-T3) differ about 100-150 bp. Explain the difference. New gel analysis of genomic DNA digested with the *Sac I* restriction enzyme, and Southern blot analysis using the *cry35Ab1* and *pat* gene probes should be performed (see figures 6 and 7).

7.1
The applicant states that the non-GM comparator has comparable genetics to 59122xNK603. There is no outline about the process of rearing this non-GM comparator. Such an outline should be presented.

7.2
Comparison between 59122xNK603 and non-GM comparator should cover more than one growing season. Comparison between 59122x1507xNK603 and non-GM should also cover locations representative of various European environments where maize can be grown.

D 7.9.02
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 59122xNK603 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 Cry34Ab1 and Cry35Ab1 proteins in food and feed from maize 59122xNK603 cannot be excluded. Thus, the Panel's view is that as the adjuvant effect of Cry34Ab1 and Cry35Ab1 with reasonable certainty cannot be excluded, the applicant in relation to a possible adjuvant effect of Cry34Ab1 and Cry35Ab1 must comment upon the mice studies showing humoral antibody response of Cry1A proteins.

Further, although the Cry34Ab1 and Cry35Ab1 proteins are 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.

References:

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