Adopted part of the minutes[1] of the 46th plenary meeting of the Scientific Panel on Genetically Modified Organisms held on 3-4 December 2008

GMO Panel deliberations on the Austrian report "Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice" as adopted at the plenary meeting of 3-4 December 2008.

On 11 November 2008 the Austrian Federal Ministry of Health, Family and Youth released a research report on studies in mice, which were conducted to assess the impact of genetically modified (GM) maize NK603 x MON 810 on reproduction (Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice, Dr. Alberta Velimirov, Dr. Claudia Binter, Univ. Prof. Dr. Jürgen Zentek).

The report includes three studies, a life-time study, a multigeneration study (MGS), and a reproductive assessment by continuous breeding study (RACB). According to the authors the life-time study showed no statistically significant differences in survival between mice fed with kernels of maize NK603 x MON 810 and the controls. They also reported that, in the MGS study, no significant differences in reproductive traits were found between mice fed with kernels of maize NK603 x MON 810 and the controls. In the RACB study, the authors used a modified protocol of the original RACB study developed at the U.S. National Toxicology Program (NTP) for the testing of chemicals. Male and female mice were housed as breeding pairs for approximately 20 weeks and allowed to produce litters continuously throughout the cohabitation period. The authors identified differences in reproductive parameters between mice fed with the GM maize and the controls. They reported that there were statistically significantly fewer pups born in the GM group in the 3rd and 4th delivery and fewer pups weaned in the 4th litter compared with the control group.

The GMO Panel considered this report and came to the following conclusions.

Regarding the RACB study, the summary Table 59 contains calculation errors and inconsistencies in the treatment of the data regarding the 3rd and 4th litters. In addition, it seems that the authors have calculated the number of pups at birth per pair and not per delivering pair, which is standard practice. Also, there appears to be methodological deficiencies in the statistical analysis that seriously compromise the interpretation of the data. For the reasons stated above, individual data are required for a proper assessment. In addition, more detailed information regarding the breeding scheme is needed. In particular, it should be clarified whether in the 3rd and 4th pairing the same or different pairs failed to reproduce.

Information regarding the normal variation of the parameters examined in this study for the mouse strain used (historical control data) is required before any conclusion may be drawn on possible alterations in reproductive performance. In addition, further information on the estrous cycle and histopathological parameters including spermatogenesis, follicle and oocyte counts is essential for assessing the claims of reduced fertility.

The GMO Panel also notes that information on the genetic identity and characteristics of the tested materials is not sufficient.
On the basis of the data presented the GMO Panel is of the opinion that no conclusions can be drawn from the report.

[1] Published at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902199319.htm. The complete minutes will be adopted at the 47th plenary meeting (28-29 January 2009) and will be published shortly afterwards.