Summary of the opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/GB/02/M3/3) for the placing on the market of glyphosate-tolerant and insect-resistant genetically modified maize NK603 x MON810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto[1]

(Question No EFSA-Q-2005-056)

Opinion adopted on 13 October 2005

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified maize NK603 x MON810 (Unique Identifier MON-ØØ6Ø3-6 x MON-ØØ81Ø-6), developed to provide protection against specific lepidopteran pests and tolerance to glyphosate.

The opinion is based on a question raised by the Commission relating to a notification for the placing on the market of NK603 x MON810 maize under Directive 2001/18/EC (Reference C/GB/02/M3/3). The question followed a scientific assessment which was made initially by the Competent Authority of United Kingdom and evaluated subsequently by all other Member States. An assessment of the NK603 x MON810 maize was requested by the Commission because of questions raised by several Member States following the evaluations at the national level. When this is the case, EU legislation requires that EFSA carries out a further assessment and provides an opinion. The GMO Panel was therefore requested to consider whether there is any scientific reason to believe that placing NK603 x MON810 maize on the market, for import, processing and use as any other maize (excluding food uses), is likely to cause any adverse effects on human health and the environment.

In its opinion, the GMO Panel took into account information from the applications for placing NK603 and MON810 maize as well as NK603 x MON810 maize (Reference EFSA-GMO-UK-2004-01) on the market where appropriate, as well as comments from the Member States. Although an overall single risk assessment of all uses, excluding cultivation, has been made for regulatory reasons, opinions for the application under Regulation (EC) No 1829/2003 and the notification under Directive 2001/18/EC are issued separately.

The single events MON810 and NK603 have been the subjects of earlier assessments. MON810 maize has been previously evaluated and approved under Directive 90/220/EEC. NK603 maize has been previously evaluated and approved under Directive 2001/18/EC. The use of food ingredients from MON810 maize and from NK603 maize were both notified under Regulation (EC) No 258/97.

[1] For citation purposes: Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/GB/02/M3/3) for the placing on the market of glyphosate-tolerant and insect-resistant genetically modified maize NK603 x MON810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto, *The EFSA Journal* (2005), 308, 1-22.

Molecular analysis of the individual inserts in NK603 and MON810 parents included information on the complete sequence of inserts and flanking regions. The GMO Panel is of the opinion that bioinformatic analysis of the DNA insert and flanking regions indicates no cause for concern. As traditional breeding methods were used in the production of NK603 x MON810 maize, no genetic modification was involved and thus the molecular structures of the DNA inserts in NK603 and MON810 were expected to remain unchanged in NK603 X MON810. This was indicated by the preservation of the phenotypes and was further confirmed using Southern blots which demonstrated that insert structures were indeed retained in NK603 x MON810 maize.

The mean levels of Cry1Ab and CP4 EPSPS proteins in forage and grain of NK603 x MON810 were not significantly different from MON810 and NK603 maize, which were previously considered safe and approved. There were large variations but within similar ranges in the expression of these proteins in NK603 x MON810 and in MON810 and NK603, respectively. The GMO Panel concludes that these data do not raise safety concerns.

The Panel found no evidence of any interactions between the newly expressed proteins Cry1Ab and CP4 EPSPS and there were no indications of altered allergenic potency of NK603 x MON810 as compared to non-modified maize. In addition, a compositional comparison of NK603 x MON810 maize with non-transgenic comparators revealed no relevant differences. The GMO Panel is therefore of the opinion that this hybrid between MON810 and NK603 maize is as safe for human and animal health as conventional maize. The Panel further concludes that experimental studies have shown NK603 x MON810 maize to be nutritionally equivalent to conventional maize.

The notification C/GB/02/M3/3 only concerns the import and use of the NK603 x MON810 maize but does not include cultivation. The GMO Panel agrees that unintended environmental effects due to adventitious establishment and spread of NK603 x MON810 maize will not be different from that of traditionally bred maize. The GMO Panel also concludes that the amounts of Cry1Ab protein being distributed onto land in animal and food waste would be very low, minimizing the possibility for exposure of potentially sensitive non-target organisms. The monitoring plan provided by the applicant is in line with the intended uses for the GMO.

In conclusion the GMO Panel considers that the information available for NK603 x MON810 maize addresses the outstanding questions raised by the Member States and considers it unlikely that NK603 x MON810 maize will have any adverse effect on human and animal health or the environment in the context of its proposed uses.

Key words: MON810, NK603, NK603 x MON810, GMO, maize, hybrid, *Zea mays*, human health, environment**,** import, food/feed safety, Regulation (EC) 1829/2003, Regulation (EC) 258/97, Directive 90/220/EEC, Directive 2001/18/EC, Regulation (EC) 1829/2003.