

This is provisional English translation of the original statement.

**Statement of the Food Safety Commission Japan (FSCJ)
toward the paper claiming development of
toxicity in maize line NK603 tolerant to the herbicide glyphosate**

**12 November 2012
Food Safety Commission Japan**

A paper, “Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize” (Séralini *et al.*), was published online, on 19 September 2012, in the scientific journal *Food and Chemical Toxicology* (2012;50:4221-31), describing that toxic effects were shown in a long-term (two-year) toxicity study in rats fed with genetically modified maize line NK603 tolerant to the herbicide glyphosate (hereinafter referred to as “NK603 maize”).

The Expert Committee on Genetically Modified Foods, a subsidiary committee of the Food Safety Commission Japan (FSCJ), reviewed the paper and reported its opinion (as in attached*) to the Commission. (**Note: in this translation, the attachment is omitted.*)

The FSCJ is of the view that the study results mentioned in the paper are insufficient to lead a certain conclusion on toxicity due to inappropriate designs of the study to determine whether or not NK 603 maize effects on human health.

The main reasons to the view above are as follows:

- 1) The study does not follow the internationally accepted guidelines on carcinogenicity testing, i.e. the study uses only 10 rats, instead of 50 rats, per treatment group, thus making it difficult to conduct regular statistic evaluations.
- 2) The study design includes only one control group which is not suitable to serve as control for all three treatment groups. It makes unacceptable to assess adverse effects in comparison between treatment groups and control groups in the study.

In the results, cancer and death were observed in the control group (rats fed with non-genetically modified maize) because the Sprague-Dawley rats, which were predisposed to pituitary and breast tumors, were inappropriately used in the two-year feeding study, namely the rats in the study fed a whole lifetime diet.

Animal number of 10 rats each in treatment and control group was inadequate and precludes judgement whether or not feed containing NK603 maize caused sickness such as cancer and death during the feeding study.

While three treatment groups of rats were fed with respectively 11%, 22% and 33% of NK603 maize in this study, there was only one control group of rats fed with 33% of non-genetically modified maize. Due to the absence of corresponding appropriate control groups, comparison between treatment and control groups of rats fed with the same rate of maize is not possible, thus toxicological effects of NK603 maize can not be judged in the study.

The Pharmaceutical Affairs and Food Sanitation Council, a consultative scientific panel of the Ministry of Health, Labor and Welfare, at that time, had examined the safety of NK603 maize as food and had concluded that there was no concern on the adverse effect on human health. To date, no new scientific findings have been identified to prove otherwise.

For the reasons above, the FSCJ is of the opinion that the study in the paper can not suggest any need to reassess the safety of NK 603 maize.

The FSCJ intends to continue gathering relevant information; however, it does not see a need at this point in time to revisit the outcome of the safety assessment of NK603 maize already evaluated.