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Statement on the analysis of data from a 90-day rat feeding study with MON 863 maize by the Scientific Panel on genetically modified organisms (GMO)

doi:10.2903/j.efsa.2007.753

EFSA Panel on Genetically Modified Organisms (GMO)**Panel Members****Acknowledgment****Type:** Statement of the Scientific Committee/Scientific Panel**Adopted:** 25 June 2007**Published:** 28 June 2007**Last updated:** 28 June 2007. This version replaces the previous one/s.**Abstract**

No abstract available

Summary

In 2004 the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) gave its opinion on the safety of MON 863 maize for import and processing, food and feed uses (EFSA, 2004a,b) and released a statement on the same topic shortly after (EFSA, 2004c). In these documents it was concluded that the MON 863 maize would not have an adverse effect on human and animal health or the environment in the context of its proposed use. One of the studies assessed by the Panel was a 90-day (subchronic) feeding study in rats using kernels of MON 863 maize (Monsanto, 2002).

Since then, two scientific papers dealing with this study have been published (Hammond et al., 2006; Séralini et al., 2007).

Hammond et al. (2006) described the study and its outcomes, but in less detail than the original report provided by Monsanto (2002). Séralini et al. (2007) published a statistical re-analysis of the original data from Monsanto and concluded that 'with the present data it cannot be concluded that GM corn MON 863 is a safe product'. The European Commission asked EFSA on 15 March 2007 to consider, in cooperation with the Member States, what impact the re-analysis might have on the earlier opinions and statement of the GMO Panel (EFSA, 2004a,b,c). In response to the question from the European Commission, EFSA set up a Task Force to assess the statistical methodology applied by Séralini et al. (2007), and to perform an additional statistical analysis. The outcome of the Task Force' analysis is reported in a document entitled: "EFSA review of statistical analyses conducted for the assessment of the MON863 90-day rat feeding study" (EFSA, 2007). In addition EFSA asked Member States whether there were any further relevant data or views on the Monsanto study and its statistical approach. EFSA also convened a technical meeting with the authors of the paper (Séralini et al. 2007) in order to have a

full understanding of their statistical considerations and approaches.

Keywords

evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission