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PRESS RELEASE

EFSA reaffirms its risk assessment of genetically modified maize MON 863

At the request of the European Commission (EC), EFSA has examined a paper by Séralini et al. on the statistical evaluation of a 90-day feeding study in animals with genetically modified maize MON 863, to identify any consequences for EFSA's risk assessment of the safety of MON 863.¹ The paper presents an alternative statistical analysis of the 90-day rat study that was considered in the original risk assessment. Following a detailed statistical review and analysis by an EFSA Task Force, EFSA's GMO Panel has concluded that this re-analysis of the data does not raise any new safety concerns.

EFSA undertook a series of actions to give a considered response to the European Commission on this issue:

- Member States (MS) were asked to provide any analyses and comments that may contribute to consideration of this issue.
- EFSA set up a Task Force of internal and external statistical experts to help assess the statistical methodology applied by authors of the publication in their re-analysis of the original data from the 90-day rat feeding study and to consider the contributions received from MS. As part of that work a meeting was held with the authors of the paper.
- EFSA's GMO Panel has reviewed all the available evidence.

Following this work, EFSA has responded to the Commission, published a statistical report and issued a scientific statement from its GMO Panel. The main conclusions are:

- The statistical analysis made by the authors of the paper did not take into account certain important statistical considerations. The assumptions underlying the statistical methodology employed by the authors led to misleading results.
- EFSA considers that the paper does not present a sound scientific justification in order to question the safety of MON 863 maize.
- Observed statistically significant differences reported by Monsanto, Séralini et al., and EFSA, were considered not to be biologically relevant. In the absence of any indications that the observed differences are indicative of adverse effects, the GMO Panel does not consider that this paper

¹ The scientific opinions are available at EFSA website at
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/381.Par.0001.File.dat/opinion_gmo_06_en1.pdf
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/383.Par.0001.File.dat/opinion_gmo_07_en1.pdf

raises new issues with respect to the safety of MON 863 maize. Therefore, the GMO Panel sees no reason to revise its previous Opinions that the MON 863 maize would not have an adverse effect in the context of its proposed use.

Prior to this most recent work, MON 863 maize has been subject to a comprehensive risk assessment by EFSA and by other authorities which did not identify any adverse effects on human and animal health or the environment. The 90-day rat study analysed by this paper is one element of the comprehensive risk assessment of MON863 maize. In addition to the original Opinion in April 2004, this study has been reviewed again twice since then, prior to this recent work.

The letter to the Commission, the GMO Panel statement, EFSA statistical analysis of the Monsanto data are available on the EFSA website at the following links:

Letter to the Commission

http://www.efsa.europa.eu/en/about_efsa/structure/who_is_who/home_cgl/correspondence.html

The GMO Panel statement

http://www.efsa.europa.eu/en/science/gmo/statements0/gmo_statement_mon863_ratfeeding.html

EFSA statistical analysis of the Monsanto data

http://www.efsa.europa.eu/en/science/scientific_reports/statistical_analyses_MON863.html

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