

EFSA publishes initial review on GM maize and herbicide study

Press Release
4 October 2012

The European Food Safety Authority has concluded that a recent paper raising concerns about the potential toxicity of genetically modified (GM) maize NK603 and of a herbicide containing glyphosate is of insufficient scientific quality to be considered as valid for risk assessment.

EFSA's initial review found that the design, reporting and analysis of the study, as outlined in the paper, are inadequate. To enable the fullest understanding of the study the Authority has invited authors Séralini *et al* to share key additional information.

Such shortcomings mean that EFSA is presently unable to regard the authors' conclusions as scientifically sound. The numerous issues relating to the design and methodology of the study as described in the paper mean that no conclusions can be made about the occurrence of tumours in the rats tested.

Therefore, based on the information published by the authors, EFSA does not see a need to re-examine its previous safety evaluation of maize NK603 nor to consider these findings in the ongoing assessment of glyphosate.

EFSA assessed the paper against recognised good scientific practices, such as internationally agreed study and reporting guidelines.

Per Bergman, who led EFSA's work, said: *“Some may be surprised that EFSA's statement focuses on the methodology of this study rather than its outcomes; however, this goes to the very heart of the matter. When conducting a study it is crucial to ensure a proper framework is in place. Having clear objectives and the correct design and methodology create a solid base from which accurate data and valid conclusions can follow. Without these elements a study is unlikely to be reliable and valid.”*

The Director of Scientific Evaluation of Regulated Products added that the consideration of possible long-term effects of GMOs has been, and will continue to be, a key focus of EFSA's work to protect animals, humans and the environment.

EFSA's preliminary review issued today is the first step in a two-stage process. A second analysis will be delivered by the end of October 2012. This will take into account any additional information from the study authors, who will be given an opportunity to supply study documentation and procedures to the Authority to ensure the broadest possible understanding of their work. It will also include an overview of Member State assessments of the paper and an analysis from the German authorities responsible for the assessment of glyphosate.

Main findings of Initial Review

The task force, whose members were drawn from the Authority's GMO, pesticide and scientific assessment units, has outlined a list of issues about the paper that would need to be resolved before it could be viewed as well-conducted and properly-reported study.

- The strain of rat used in the two-year study is prone to developing tumours during their life expectancy of approximately two years. This means the observed frequency of tumours is influenced by the natural incidence of tumours typical of this strain, regardless of any treatment. This is neither taken into account nor discussed by the authors.
- The authors split the rats into 10 treatment sets but established only one control group. This meant there was no appropriate control for four sets – some 40% of the animals - all of whom were fed GM maize treated or not treated with a herbicide containing glyphosate.
- The paper has not complied with internationally-recognised standard methods – known as protocols - for setting up and carrying out experiments. Many of these procedures are developed by the OECD (Organisation for Economic Cooperation and Development).
- For a study of this type, the relevant OECD guideline specifies the need for a minimum of 50 rats per treatment group. Séralini *et al* used only 10 rodents per treatment set. The low number of animals used is insufficient to distinguish between the incidence of tumours due to chance rather than specific treatment effects.
- The authors have not stated any objectives, which are the questions a study is designed to answer. Research objectives define crucial factors such as the study design, correct sample size, and the statistical methods used to analyse data - all of which have a direct impact on the reliability of findings.
- No information is given about the composition of the food given to the rats, how it was stored or details of harmful substances – such as mycotoxins – that it might have contained.
- It is not possible to properly evaluate the exposure of the rats to the herbicide as intake is not clearly reported. The authors report only the application rate of the herbicide used to spray the plants and the concentration added to the rats' drinking water but report no details about the volume of the feed or water consumed.
- The paper does not employ a commonly-used statistical analysis method nor does it state if the method was specified prior to starting the study. The validity of the method used is queried and there are questions over the reporting of tumour incidence. Important data, such as a summary of drop outs and an estimation of unbiased treatment effects have not been included in the paper.
- Many endpoints – what is measured in the study – have not been reported in the paper. This includes relevant information on lesions, other than tumours, that were observed. EFSA has called on the authors to report all endpoints in the name of openness and transparency.
- Review of the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603
- Letter to Prof. Séralini regarding EFSA's Review of the Séralini et al. (2012) publication on a 2-year rodent feeding trial with Glyphosate Formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology, 4 October 2012

Notes to editors:

EFSA set up a multi-disciplinary task force in response to an urgent request from the European Commission to evaluate a paper by Séralini *et al* to assess whether its findings could lead the Authority to reconsider its previous opinion on maize NK603. The two-year study, published in the journal Food and Chemical Toxicology on 19 September 2012, has suggested that consumption of the GM maize and a herbicide containing glyphosate at levels below officially-safe limits are linked to a reported increase in incidence of tumours in rats.

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