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**Opinion of the Czech Scientific Committee on Genetically Modified Food and Feed
(CSCGMFF)**

on

EFSA statement to article “Gilles-Eric Séralini, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin, Joël Spiroux de Vendômois (2012) Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food and Chemical Toxicology, <http://dx.doi.org/10.1016/j.fct.2012.08.005>)”

No.	EFSA main findings	Opinion of the CSCGMFF
1	The strain of rat Virgin albino Sprague-Dawley rats 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.	We fully agree with this scientific view
2	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.	We fully agree with this scientific view
	The paper has not complied with internationally-recognised standard methods - known as	We fully agree with this scientific view

3	protocols - for setting up and carrying out experiments. Many of these procedures are developed by the OECD (Organisation for Economic Cooperation and Development).	
4	For a study of this type, the relevant OECD guideline specifies the need for a minimum of 50 rats per treatment group (i.e. OECD 451 and OECD 453). Seralini et al 2012 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.	We fully agree with this scientific view
5	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.	We fully agree with this scientific view
6	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.	We fully agree with this scientific view With regards to mycotoxins it concerns aflatoxins and fumonisins
7	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.	We fully agree with this scientific view
8	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,	We fully agree with this scientific view

	such as a summary of drop outs and an estimation of unbiased treatment effects have not been included in the paper.	
9	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.	We fully agree with this scientific view

Conclusions:

We fully agree that the study, as described in the Séralini et al. (2012) publication, is inadequately reported with many key details of the design, conduct, analysis and reporting being omitted. Without such details it is impossible to give weight to the subsequent results.

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