

EUROPEAN COMMISSION HEALTH & CONSUMERS DIRECTORATE-GENERAL

Deputy Director General for the food chain

Brussels, SANCO/E1/SP/lav Ares (2012) 1278483

Dear Ms Geslain-Lanéelle,

Subject: New study entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize"

DG SANCO has been made aware of a research paper published on 19 September 2012 in the Food and Chemical Toxicology Journal and entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize."¹

The health effects of NK603 maize cultivated with or without Roundup and Roundup alone were studied during 2 years in rats. The authors of the study conclude that lower levels of glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances in rats. Similarly, disruption of biosynthetic pathways that may result from overexpression of the EPSPS transgene in the GM NK603 maize can give rise to comparable pathologies that may be linked to abnormal or unbalanced phenolic acid metabolites or related compounds.

As regards glyphosate, consistently with similar actions taken in the past, the Commission is asking in parallel as a matter of urgency Germany, Rapporteur Member State for this substance, to evaluate the new study.

I would be grateful if you could review the scientific publication and ask any clarification needed to the authors of the paper. In particular, as regards the GM aspects, I would like you to indicate whether the publication contains new scientific elements that could lead EFSA to reconsider the outcome of its opinions on NK603 and its stacks.

Ms Geslain-Lanéelle Executive Director European Food Safety Authority Via Carlo Magno 1/a I-43126 Parma

¹ Séralini GE, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, Vendômois JS – Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize; *Food Chem. Toxicol.* 2012

I would also invite you to take into consideration the assessment of Member States evaluation agencies on the matter including the relevant German authorities responsible for the evaluation of glyphosate.

Given the importance of the issue, I would appreciate an answer as a matter of urgency.

Yours sincerely,

[SIGNED]

^{*} Ladislav Miko

<u>E-mail copy</u>: Ms E. Waigmann, Ms C. Paoletti, Mr H. Fontier, Mr L. Mohimont (EFSA);
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