

Recent EU Safety Testing Debunks (Séralini's) Claims that GMOs Cause Cancer

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Background

It would be recalled that in the year 2012, Séralini *et al.* reportedly found evidence that food derived from GMOs and GM crops [specifically NK603 maize] treated with Glyphosate [also called Roundup®] can cause cancer and increase the chances of death in rats. This study was first published in a reputable scientific journal called the *Food and Chemical Toxicology* (FCT) journal. Subsequently, the study was widely criticized based on extensive and thorough reviews by experts in the scientific community and global regulatory authorities. The reviews revealed that the study used seriously flawed methods that did not accord with best practices and that the conclusions were therefore not supported by the results provided. The findings were also inconsistent with the large body of published safety data as well as the long history of safe use of NK603 and Roundup herbicide. These review outcomes and a series of protest letters to the editor of the journal led to a conclusion that the paper did not meet the requisite scientific standards for publication in the journal. Consequently, the paper was withdrawn from the journal in 2013. The details of these highlighted events were captured in [three separate briefs](#) previously circulated by ABNE.

Subsequently, the European Commission requested the European Food Safety Authority (EFSA) to assist the Commission to provide supplementary guidance on key elements to consider for conducting 2-year carcinogenicity trial in rats in the evaluation of genetically-modified food/feed. In response to this, a collaborative project of the EU's Seventh Framework Programme for research, technological development and demonstration, known as 'Genetically Modified Plant (GMP) Two Year Safety Testing' ([G-TwYST](#)) was carried out within the context of the request from the EC. It also was designed to address lingering concerns such as the 'long-term toxicity of a Roundup-tolerant genetically modified maize'^{1,2}. The findings were recently announced and revealed that there were no toxic or carcinogenic effects arising from the consumption of the GM maize NK603 during the animal feeding studies. This brief therefore, aims to highlight the conclusions from the G-TwYST project with respect to the long-term toxicity studies and the implication on GM regulation in Africa to serve as a guide to African biosafety regulators, and policy- and decision-makers.

¹ Séralini GE *et al.*: first published in *Food Chem. Toxicol.* 50: 4221-4231, 2012; retracted in *Food Chem. Toxicol.* 63: 244, 2014; republished in *Environ. Sci. Eur.* 26: 14, 2014.

² EFSA (2012) Final review of the Séralini *et al.* (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in *Food and Chemical Toxicology*. *EFSA J.* 10: 2986.

Safety testing on GM maize

The purpose of the G-TwYST project was to come up with ways to better test the long term safety of GM foods (following claims of cancer) using international best practices and standards set by the OECD and EFSA. It is also to determine whether there is value in conducting such long-term safety studies in assessing the long-term safety of GMOs. To do this, the EU research team conducted three rat feeding studies with GM maize NK603 without and with a Roundup application including:

- two 90-day trials for subchronic toxicity testing, and
- one combined chronic toxicity/carcinogenicity study lasting for 2 years.

They also engaged and reviewed findings from other relevant research on the safety of GMOs including:

- the GMO Risk Assessment and Communication of Evidence ([GRACE](#)) project with GM maize MON810, and
- the [GMO90+](#) project conducted in France with both GM maize plants (NK603 and MON810);
- complimentary investigation into broader societal issues;
- inclusive and responsive stakeholder engagement; among others.

Research findings and conclusions

At the end of the G-TwYST study, researchers did not find any potential long-term health effects associated with food derived from GMOs and Crops treated with Glyphosate. This support the conclusion made originally from earlier risk assessments published by EFSA³. Also, the GRACE and GMO90+ research did not identify any potential risk for human and animals. In a statement released by the researchers (in the form of a [Policy Brief](#)) they concluded that

“Neither the 90-day nor the long-term animal studies revealed any health risks of the GM maize tested. These findings support the conclusions based on previous steps of the risk assessment comprising the initial molecular characterization of the genetic modification as well as the phenotypic, agronomic, and compositional analyses of the GM line in relation to its conventional counterpart and other non-GM lines.”

³ EFSA (2003) Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of food and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto, The EFSA Journal (2003) 9, 1-14.

and

“In contrast to a study conducted earlier (Séralini et al., 2012/2014), the 2-year carcinogenicity animal feeding study performed by G-TwYST did not reveal any potential health risk associated with GM maize NK603.”

Furthermore, considering that the results of all three studies (90-day and 2-year feeding studies) are consistent in terms of their finding of no adverse effects, the researchers concluded that there is no need for routinely requiring long term feeding studies in evaluating transgenic food crops.

Implication on GM regulation in Africa

The findings from these projects provide further evidence that the conclusions from the controversial GM maize study by Séralini *et al.* were fatally flawed and cannot be used for any regulatory or policy decision making. They also further strengthen the large body of evidence that GM foods do not present any new risks. It is notable that some African governments, policy makers and regulatory institutions have based vital policy decisions on the very flawed findings of the Séralini *et al.* studies. As earlier stated in the [ABNE Biosafety Brief 2013](#), “any negative decisions regarding GMOs based on this study lack merit and are scientifically unjustifiable”. There is therefore a need for a careful re-evaluation of any such decisions.

ABNE’s position

ABNE has always maintained its position in support of the large body of evidence gathered till date by the scientific community and global regulatory authorities on the fact that GMOs are not less safe than their conventional counterparts until the availability of a sound scientific evidence in negation. Also, recall that ABNE proposed that in order for the controversy to be completely laid to rest, a repeat of the study should be considered, though existing studies on long-term feeding trials of other GM crops to rats have not revealed any adverse effects. The G-TwYST project has addressed the need for a repeat of the study and the findings have contributed significantly to the growing body of evidence demonstrating that GM foods are as safe as their conventional counterparts. We are committed to sustained capacity building of regulators, and policy- and decision-makers to ensure that biosafety applications are considered on a case-by-case basis, totality of safety proofs are weighed, and science-based evidence informs decisions.

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This was developed by the African Biosafety Network of Expertise (ABNE) to address possible fall-outs from the 'French rat study'. This brief is primarily for regulators, policy-developers and decision-makers.

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