

FOLLOW-UP ON CONTROVERSIAL GM MAIZE STUDY BY *SERALINI et al*; European Food Safety Authority confirms their conclusion that the study is not valid for risk assessment

Background

It will be recalled that ABNE on October 14th 2012 [published a brief](#) to provide African regulators with accurate information on reviews by experts of a study by Seralini et al., 2012 [\(1\)](#)¹ which reported adverse health effects and premature death in rats fed glyphosate herbicide and glyphosate tolerant GM Maize (NK603). In that brief, ABNE clearly articulated views by experts and competent national and international food safety authorities on the study, all of which concluded that the study is seriously flawed in many ways and does not contribute any significant new information towards the risk assessment of genetically modified foods or glyphosate itself. Since then, there have been a number of new developments on this study that are fully consistent with these earlier reviews. In this brief, we wish to highlight some of these current developments and to provide a comprehensive list of useful information resources that can help regulators and scientist make further decisions on the study and advise their governments accordingly. It is the belief of ABNE that this current information will bring clarity to African regulators and policy makers on the weight to be placed on this GM maize study.

EU rejects the French Rat Study

Recently, EFSA published its final verdict [\(2\)](#) on the GM maize study by *Seralini et al. 2012 (1)* after additional review and consideration of a response published by Seralini et al [\(3\)](#) to address criticisms of their study. EFSA reiterated its conclusion that: “there are serious defects in the design and methodology of a paper by Séralini et al. and thus it does not meet acceptable scientific standards to warrant the re-examination of previous safety evaluations of genetically modified maize *NK603* or its stacks”. This final review was published together with independent reviews by six (6) European Union member states all of which reached similar negative conclusions (Annexed to the main EFSA report).

¹ Numbered In-chapter references are **stand-alone links to referenced documents/webpages** and are also part of the additional information resources listed in **Table 1** (NOT NECESSARILY IN THE SAME ORDER AS IN DOCUMENT)

In addition to EFSA's review, several other regulatory authorities worldwide including the Canadian (4), Brazilian (5), and Australian/New Zealand (6) food safety authorities have reviewed this study, and have all raised similar strong concerns regarding the scientific quality and inappropriate conclusions of this study.

Commission of enquiry; French government rejects French Rat Study

The French government launched a commission of enquiry into the study charging two of its national agencies, the High Council for Biotechnology (HCB) (7) and the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) (8a, 8b) to establish the veracity of the study for necessary action. After holding hearings with the authors and obtaining raw data from them, the expert group concluded separately that "the study provides no scientific information regarding the detection of any health risk linked to NK603 corn, whether it was treated with Roundup or not" and "that though the study was an ambitious one, the conclusions advanced by authors are not sufficiently supported by the data presented in the publication". This conclusion is consistent with a similar report from the French Academies of Sciences which, in a rare event, also rejected the findings of this study (9).

Scientific Peer-review; only a first step to establishing scientific veracity of published studies

How could a study almost universally regarded as seriously flawed and misleading be published in a respected journal? It is important for regulators to note that the fact that an article is peer-reviewed does not bring finality to the findings in the article, nor does peer review always meet the goals of ensuring that the results are valid and meaningful. There are several levels of checks involved in establishing the veracity of published scientific information; first is the peer-review process by two or three scientists selected by the editorial board of the journal, and then analysis by the scientific community as a whole during which the published information is more widely examined and critiqued. Finally, additional studies may be conducted when necessary to clarify any important issues raised. Clearly, the Seralini study has just gone through this second phase of scientific peer-review by the broader scientific community and has failed this review. In this case the initial peer review has also come under considerable criticism from other scientists e.g. the European Federation of Biotechnology ([press release by Em Prof. M. Van Montagu; pioneer of modern biotechnology](#)) described the publication of this study as "a dangerous case of failure of the peer-review system" and the French Academies of Science stated that "the journal should never have accepted this article". A large number of scientists have independently communicated with the editor of the journal expressing strong criticism of the Seralini paper citing serious inconsistencies ([see letters to editor in Table 1](#)). The next step may be for scientists to conduct additional studies to clarify the issues generated by this study. However, previous studies ([see previous published studies on GMO safety in Table 1](#)) have not supported the claims by the Seralini group regarding the toxic effects of either glyphosate-resistant GM crops or of glyphosate itself. The safety assessment of GM crops is a serious and challenging endeavor, but safety can only be assured if decisions are based on credible science.

This is likely to be an on-going controversy and we will continue to monitor developments and provide updates as appropriate.

Additional Information Resources

Below is a list of useful links to information on the controversial French Rat Study. **We have taken the liberty to provide information from both sides of the discussion so regulators can make an informed choice.** It is our hope that regulators and policy makers will take time to read this information and advise their governments appropriately (especially the ANSES and EFSA final reports).

Table 1: Useful links to information on the French Rat Study controversy

Papers published by Seralini et al., 2012	Links
Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize	link
Answers to critics: Why there is a long term toxicity due to NK603 Roundup-tolerant genetically modified maize and to a Roundup herbicide	link
Review by Regulatory Authorities	
EFSA (European Food Safety Authority) Initial Assessment	link
EFSA Final opinion	link
Germany- BfR (Institute for Risk Assessment)	link
Germany- BVL (Federal Office of Consumer Protection and Food Safety): <i>in German</i>	link
FSANZ (Australia New Zealand Food Standards)	link
France- ANSES (Agency for Food, Environmental, and Occupational Health and Safety)	link
Scientific report – French	
Scientific report – English	link
France- HCB (High Counsel for Biotechnology)-	Press release- French link
	Press release- English link
	Scientific Committee report- French link
	Scientific Committee Executive Summary- English link
	Economic, Ethical and Social Committee- French link
Denmark- DTU National Food Institute	link
Netherlands- Bureau for Risk Assessment (Netherlands Food and Consumer Product Safety Authority)	link
Brazil- CTNBio (Brazilian National Technical Commission on Biosafety)- Portuguese	link
	English link
Canada- Health Canada-	English link
	French link
Belgium- BAC (Biotechnology Advisory Council)	link
Romania (Food Safety Authority)	link
Review by selected Scientific Bodies	
Six French Academies of Science (Académies nationales d’Agriculture, de Médecine, de Pharmacie, des Sciences, des Technologies, et Vétérinaire) Press Release (French)	link
	Report (French) link
Belgium- VIB (Life Sciences Institute)	link
French Society of Toxicological Pathologists (SFPT)	link

European Society of Toxicological Pathologists (ESTP)	link
European Federation of Biotechnology (EFB)	link
AFBV (French Association for Biotechnology Vegetables)	link
ABNE (African Biosafety Network of Expertise)	link
ACB (African Center for Biosafety)	link
Letters to the Editor of Food and Chemical Toxicology	
Berry	link
Cockburn	link
deSouza	link
Dung	link
Grunewald	link
Hammond, Goldstein, and Saltmiras (Monsanto)	link
Heinemann	link
Langridge	link
Olivier	link
Panchin	link
Pilu	link
Schorsch	link
Tester	link
Trewavas	link
Tribe	link
Wager	link
Williams	link
Animal Rights Organizations	
BUAV (BUAV simply operates under these initials, historically this was the British Union of Anti-Vivisectionists)	link
ECEAE (European Coalition to End Animal Experiments)	link
NK603 Maize Risk Assessment, Approvals and Fact Sheet	
Risk assessment and regulatory approvals (CERA Database)	link
Factsheet on NK603 maize	link
Previously published long term studies on the safety of GM Foods and Glyphosate	
Snell et al, 2012	link
Domingo et al, 2011	link
Malatesta et al, 2008	link
Sakamoto et al, 2008	link
Sakamoto et al, 2007	link
Domingo et al, 2007	link
Hammond et al, 2004	link
European Commission funded research (130 projects involving 500 independent research groups over 25 years)	link
Glyphosate based herbicides	Annex 3: ANSES Report

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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