

Home > Food & Nutrition > Genetically Modified (GM) Foods & Other Novel Foods

Food and Nutrition

Health Canada and Canadian Food Inspection Agency statement on the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603

Food Directorate
Health Products and Food Branch
Health Canada

Animal Feed Division
Animal Health Directorate
Canadian Food Inspection Agency

Pest Management Regulatory Agency
Health Canada

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In September 2012, the scientific team headed by Dr. Gilles-Eric Séralini at the University of Caen in France published the results of a long term toxicity study of Roundup Ready Maize NK603 and the herbicide Roundup (glyphosate-containing products) in the journal *Food and Chemical Toxicology* [G.-E. Séralini et al. *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize* Food Chem. Toxicol. (2012)].

Following a review of the published data, scientists from Health Canada and the Canadian Food Inspection Agency (CFIA) have identified significant shortcomings in the study design, implementation and reporting. The methodology used was inadequately described, the full data set was not presented, and the data that was reported was not presented in a transparent manner. Furthermore, the statistical methods used by the authors to analyse the data were judged to be inappropriate. These limitations make the validity of the study results difficult to determine.

In reviewing the study by G.-E. Séralini et al., Health Canada and CFIA scientists considered both industry supplied regulatory safety dossiers as well as published scientific literature with respect to NK603 corn and the herbicide glyphosate. Based on Health Canada and CFIA's review of this information, the authors' conclusions concerning the long term safety of NK603 corn and glyphosate are not supported. As a result, Health Canada and CFIA scientists have concluded that no change to the existing authorization of Roundup Ready Maize NK603 or the herbicide glyphosate would be recommended at this time. To permit further comprehensive analysis, Health Canada and the CFIA have requested the complete set of raw data from the study authors.

Reviews of this paper have also been published by the German Federal Institute for Risk Assessment (BfR)ⁱ, the European Food Safety Authority (EFSA)ⁱⁱ, Food Standards Australia New Zealand (FSANZ)ⁱⁱⁱ, and the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)^{iv}. All of these reviews concluded that study design, the presentation and interpretation of the data are flawed. As such, all four agencies concluded that it was not possible to give weight to the study results and concluded

that there was no reason to revisit the safety evaluation of NK603. These food safety assessment bodies also requested that the authors of the study provide them with raw data for further analysis.

Roundup Ready Maize NK603 is a herbicide tolerant maize variety first approved for Canadian food and feed use in 2001. Health Canada and the CFIA evaluated an extensive array of molecular, toxicological, nutritional and chemical testing data on NK603 prior to authorizing its use in Canada. Roundup Ready maize NK603 is also currently permitted for use as a food and feed in many countries and its safety has been carefully examined by health authorities around the world. The herbicide glyphosate and products containing glyphosate (e.g., Roundup) are registered pesticides in Canada supported by extensive scientific data that meet strict health and environmental standards.

The overwhelming body of scientific evidence continues to support the safety of NK603, genetically modified food and feed products in general, and glyphosate containing herbicides. However, whenever new information concerning the safety of an authorized product arises, this new data is carefully reviewed. Should any risks of concern be identified from the consumption of NK603 or exposure to glyphosate, Health Canada and the CFIA will take appropriate action.

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- i [!\[\]\(cf5be311f7b2821912d8009884508fa2_img.jpg\) A study of the University of Caen neither constitutes a reason for a re-evaluation of genetically modified NK603 maize nor does it affect the renewal of the glyphosate approval](#)
 - ii [!\[\]\(9804e70d96ff9fe9899b264c06a33cd7_img.jpg\) EFSA publishes initial review on GM maize and herbicide study](#)
 - iii [!\[\]\(4f49380f3d6bce047bc47b2072cc076f_img.jpg\) Response to Séralini paper on the long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize](#)
 - iv [!\[\]\(73944fd4f6fb83e4c64013731d1820cc_img.jpg\) AVIS de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'analyse de l'étude de Séralini et al. \(2012\) "Long term toxicity of a ROUNDUP herbicide and a ROUNDUP-tolerant genetically modified maize" \(PDF version\)](#)

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