

SÉRALINI ET AL. GM CORN SAFETY STUDY IN CONTEXT Introduction and Basic Comparison

INTRODUCTION

A team of French researchers, led by molecular biologist and endocrinologist Professor Gilles-Éric Séralini of the University of Caen in France, has published a two-year study of Monsanto's genetically engineered (genetically modified or GM) herbicide-tolerant corn NK603. The researchers studied the impacts of GM corn consumption on rats, with and without Monsanto's Roundup herbicide, and of Roundup alone. The feeding trial was conducted over the lifetime of laboratory rats and showed adverse health impacts after the 90-day period when most other studies on GM foods end. The researchers observed mammary tumours, and kidney and liver damage, leading to premature death.

This study suggests that in order to detect such possible adverse impacts government regulators need to:

- 1) require feeding trials, and,
- 2) require that such trials be long enough to explore possible chronic health impacts.

As with any scientific study, discussion, debate, and further study are necessary.

BASIC COMPARISON

The following is a simple comparison of the new independent study (Séralini et al.) with what Monsanto and Health Canada have produced on this particular GM corn.

HEALTH CANADA

Health Canada has not conducted any tests on NK603 (or on any other GM food). **In 2001, Health Canada approved Monsanto's GM Roundup Ready Corn Line 603** for human consumption, based on a data package submitted by Monsanto. This data is not accessible to the public, so we cannot comment on its contents. Health Canada did, however, publish a 3-page summary of their 2001 decision. The summary makes no reference to a feeding trial, but does refer to a gavaging study, in which mice were force-fed a high dose of the single purified protein coded for by the modified Roundup Ready gene.

Novel Food Information, Health Canada
http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/roundup_ready_corn_603-mais_603_roundup_ready-eng.php

MONSANTO

In 2004, 4 years after Health Canada approved this GM corn for human consumption, Monsanto published a 90-day feeding trial. The study was published in the peer-reviewed journal *Food and Chemical Toxicology*.

Hammond et al. 2004. "Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn." *Food Chem Toxicol* 42:1003-1014

SÉRALINI ET AL.

On September 19, 2012, a team of independent scientists in France published a two-year study of Monsanto's GM herbicide-tolerant corn NK603 in the peer-reviewed journal *Food and Chemical Toxicology*. The study was conducted over the lifetime of laboratory rats and compared the impacts of Monsanto's GM corn, both with and without the herbicide Roundup, as well as of Roundup alone.

Séralini et al. 2012. "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize." *Food Chem Toxicol*. <http://dx.doi.org/10.1016/j.fct.2012.08.005>

BACKGROUND

NK603: NK603 is the identifying number for a herbicide-tolerant (Roundup Ready) GM corn event developed by Monsanto and approved in Canada in 2001. NK603 contains two copies of the CP4-EPSPS gene controlled by one of two promoters: the enhanced CaMV 35S promoter or a rice actin promoter. The event was developed through biolistic transformation, i.e. gene gun, using one construct that contained both copies of the herbicide tolerance gene. The transgene CP4-EPSPS from the C4 strain of *Agrobacterium sp.* confers tolerance to glyphosate, the active ingredient in Monsanto's herbicide Roundup.

SÉRALINI ET AL.: The new study was conducted by a team of researchers led by molecular biologist and endocrinologist, Professor Gilles-Éric Séralini of the University of Caen in France. The study acknowledges the support of Association CERES, the Foundation Charles Leopold Mayer pour le Progrès de l'Homme, the French Ministry of Research, and the Committee of Research and Independent Information on Genetic Engineering (CRIIGEN). Professor Séralini is also president of CRIIGEN. He was previously a member of two French government committees assessing the safety of GM food. In 2007, his research team published a re-analysis of Monsanto's 90-day rat feeding study on its GM insect-resistant corn, MON863. The re-analysis showed that the rats fed MON863 had reduced growth and signs of liver and kidney toxicity. Séralini recommended that such studies be extended beyond 90 days so that the consequences of the initial signs of toxicity could be investigated.

MONSANTO COMPANY: Monsanto developed and owns the genetically engineered event NK603 that has been incorporated into many GM corn hybrids currently marketed to farmers in Canada, including Genuity VT Double PRO (GENVT2P), Herculex 1 (HX1) w RR2- Liberty Link and RR, and YieldGard CB (YGCB) w/RR2. Monsanto has not used NK603 in its new GM sweet corn series (released on the market for the 2012 growing season). It is the largest seed company in the world.

HEALTH CANADA: Health Canada is the federal government agency that evaluates the safety of GM foods for human consumption. The department does not conduct its own tests. Instead, it approves GM foods after evaluating documentation submitted by the proponent, which may be a corporation such as Monsanto, or an entity such as the Crop Development Centre of the University of Saskatchewan (proponents of a GM flax that was approved but is not on the market). Health Canada does not require animal feeding trials in order to assess the safety of new GM foods, and approved NK603 in 2001, before any feeding trials were published.

PEER-REVIEW: Peer review is the process by which a paper submitted to a scientific journal is systematically reviewed by several other scientists, to ensure adherence to sound scientific standards. As the Royal Society of Canada's 2001 Expert Panel on the Future of Food Biotechnology explained, "Peer review and independent corroboration of research findings are axioms of the scientific method, and part of the very meaning of the objectivity and neutrality of science." (p.214)

RELEVANT RECOMMENDATIONS FOR REGULATORY REFORM

Of the data behind Health Canada's decisions to approve GM foods in Canada, the Royal Society of Canada's 2001 Expert Panel on the Future of Food Biotechnology (commissioned by the government) found that, "there is no means of independent evaluation of either the quality of the data or the statistical validity of the experimental design used to collect those data." (p.214)

A key recommendation was as follows:

"The Panel recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non governmental) and independent panel of experts. The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review." (p.xi)

In addition, and among 58 recommendations in total, the Expert Panel recommended that:

- The design and execution of all testing regimes of new transgenic organisms should be conducted in open consultation with the expert scientific community.
- Analysis of the outcomes of all tests on new transgenic organisms should be monitored by an appropriately configured panel of “arms-length” experts from all sectors, who report their decisions and rationale in a public forum.
- Regulatory officials should establish clear criteria regarding when and what types of toxicological studies are required to support the safety of novel constituents derived from transgenic plants.
- An independent committee should evaluate both the experimental protocols and the data sets obtained before approvals of new plants with novel traits are granted.

The federal government did not implement any of the above recommendations.

FOR DETAILS, SEE:

Andrée, Peter. “GM food regulation: An analysis of efforts to improve genetically modified food regulation in Canada”, *Science and Public Policy*, volume 33, number 5, June 2006.

Andrée, Peter and Sharratt, Lucy. “Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada’s Recommendations?” October 2004.

<http://www.cban.ca/Resources/Topics/Regulation-and-Policy>

For access to the Royal Society of Canada’s Expert Panel Report <http://www.rsc-src.ca/en/expert-panels/rsc-reports/elements-precaution-recommendations-for-regulation-food-biotechnology-in>

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For further information and discussion of the study see

<http://www.cban.ca/Resources/Topics/Human-Health-Risks>

For a detailed discussion of safety studies and regulations see Fagan et al.

“GMOs Myths and Truths” Earth Open Source, 2012

http://earthopensource.org/files/pdfs/GMO_Myths_and_Truths/GMO_Myths_and_Truths_1.3.pdf

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