

Monsanto's Roundup-Ready GMO Maize Causes Serious Health Damage

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Global Research, June 25, 2014

The Ecologist

Region: <u>Europe</u> Theme: <u>Biotechnology and GMO</u>, <u>Environment</u>, <u>Science and Medicine</u>

A highly controversial paper by Prof Gilles-Eric Séralini and colleagues has been republished after a stringent peer review process.

The <u>chronic toxicity study</u> examines the health impacts on rats of eating a commercialized genetically modified (GM) maize, Monsanto's NK603 glyphosate-based herbicide Roundup.

The original study, published in Food and Chemical Toxicology (FCT) in September 2012, found severe liver and kidney damage and hormonal disturbances in rats fed the GM maize and low levels of Roundup that are below those permitted in drinking water in the EU.

However it was retracted by the editor-in-chief of the Journal in November 2013 after a<u>sustained campaign</u> of criticism and defamation by pro-GMO scientists.

Toxic effects were found from the GM maize tested alone, as well as from Roundup tested alone and together with the maize. Additional unexpected findings were higher rates of large tumours and mortality in most treatment groups.

Criticisms addressed in the new version

Now the <u>study has been republished</u> by *Environmental Sciences Europe*. The republished version contains extra material addressing criticisms of the original publication.

The raw data underlying the study's findings are also published – unlike the raw data for the industry studies that underlie regulatory approvals of Roundup, which are kept secret. However, the new paper presents the same results as before and the conclusions are unchanged.

The republication restores the study to the peer-reviewed literature so that it can be consulted and built upon by other scientists.

The republished study is accompanied by a <u>separate commentary by Prof Séralini's</u> <u>team</u>describing the lobbying efforts of GMO crop supporters to force the editor of FCT to retract the original publication.

The authors explain that the retraction was "a historic example of conflicts of interest in the scientific assessments of products commercialized worldwide."

"We also show that the decision to retract cannot be rationalized on any discernible scientific or ethical grounds. Censorship of research into health

risks undermines the value and the credibility of science; thus, we republish our paper."

Paper subjected to extraordinary scrutiny and peer review

Claire Robinson, editor of <u>GMOSeralini.org</u>, commented: "This study has now successfully passed no less than three rounds of rigorous peer review."

First the paper was peer reviewed for its initial publication in *Food and Chemical Toxicology*, and <u>according to the authors</u> it passed with only minor revisions.

The second review involved a non-transparent examination of Prof Séralini's raw data by a secret panel of unnamed persons organized by the editor-in-chief of FCT, A. Wallace Hayes, in response to criticisms of the study by pro-GMO scientists.

In a <u>letter to Prof Séralini, Hayes admitted</u> that the anonymous reviewers found nothing incorrect about the results, but argued that the tumour and mortality observations in the paper were *"inconclusive"*, and this justified his decision to retract the study:

"A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumor incidence. Given the known high incidence of tumors in the Sprague-Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups."

"The rationale given for the retraction was <u>widely criticized by scientists</u> as an act of censorship and a bow to the interests of the GMO industry", says Robinson.

"Some scientists pointed out that numerous published scientific papers contain inconclusive findings, including Monsanto's own short (90-day) study on the same GM maize, and have not been retracted.[9] The retraction was even condemned by a former member of the editorial board of FCT."

Now the study has passed a third peer review arranged by the journal that is republishing the study, *Environmental Sciences Europe*.

Let the critics carry out their own studies

Dr Michael Antoniou, a molecular geneticist based in London, commented, "Few studies would survive such intensive scrutiny by fellow scientists.

"The republication of the study after three expert reviews is a testament to its rigour, as well as to the integrity of the researchers. If anyone still doubts the quality of this study, they should simply read the republished paper. The science speaks for itself.

"If even then they refuse to accept the results, they should launch their own research study on these two toxic products that have now been in the human food and animal feed chain for many years."

Dr Jack A Heinemann, Professor of Molecular Biology and Genetics, University of Canterbury New Zealand, said: "I applaud Environmental Sciences Europe for submitting the work to yet another round of rigorous blind peer review and then bravely standing by the process and the recommendations of its reviewers, especially after witnessing the events surrounding the first publication.

"This study has arguably prevailed through the most comprehensive and independent review process to which any scientific study on GMOs has ever been subjected."

'Significant biochemical disturbances and physiological failures'

The study examines the health effects on rats of eating Roundup-tolerant NK603 genetically modified (GM) maize (from 11% in the diet), cultivated with or without Roundup application, and Roundup alone (from 0.1 ppb of the full pesticide containing glyphosate and adjuvants) in drinking water. It found:

- * "Biochemical analyses confirmed very significant chronic kidney deficiencies, for all treatments and both sexes; 76% of the altered parameters were kidney-related.
- * "In treated males, liver congestions and necrosis were 2.5 to 5.5 times higher. Marked and severe nephropathies were also generally 1.3 to 2.3 times greater.
- * "In females, all treatment groups showed a two- to threefold increase in mortality, and deaths were earlier.
- * "This difference was also evident in three male groups fed with GM maize.
- * "All results were hormone- and sex-dependent, and the pathological profiles were comparable.
- * "Females developed large mammary tumors more frequently and before controls;
- * "the pituitary was the second most disabled organ;
- "the sex hormonal balance was modified by consumption of GM maize and Roundup treatments.
- "Males presented up to four times more large palpable tumors starting 600 days earlier than in the control group, in which only one tumor was noted.
- "These results may be explained by not only the non-linear endocrine-disrupting effects of Roundup but also by the overexpression of the EPSPS transgene or other mutational effects in the GM maize and their metabolic consequences.
- "Our findings imply that long-term (2 year) feeding trials need to be conducted to thoroughly evaluate the safety of GM foods and pesticides in their full commercial formulations."

The paper concludes:

"Taken together, the significant biochemical disturbances and physiological

failures documented in this work reveal the pathological effects of these GMO and R treatments in both sexes, with different amplitudes.

"They also show that the conclusion of the Monsanto authors that the initial indications of organ toxicity found in their 90-day experiment were not 'biologically meaningful' is not justifiable.

"We propose that agricultural edible GMOs and complete pesticide formulations must be evaluated thoroughly in long-term studies to measure their potential toxic effects."

Regulators must take these results seriously

Dr Heinemann commented:

"The work provides important new knowledge that must be taken into account by the community that evaluates and reports upon the risks of genetically modified organisms, indeed upon all sources of pesticide in our food and feed chains."

According to Patrick Holden, Chief Executive of the <u>Sustainable Food Trust</u> (SFT) the study highlights the inadequacy of current safety testing:

"The most obvious deficiency relates to the fact that the current approval process is based on animal feeding trials of only 90 days, a totally inadequate duration when one considers that chronic diseases in animals and humans do not usually manifest until mid-life."

A second deficiency, he added, relates to the newly emerging science of epigenetics – which demonstrates that endocrine systems can be seriously disrupted by the presence of chemical residues at concentrations as low as a few parts per billion.

"This turns on its head the logic of an approval process based on MRL (maximum residue levels), since it is becoming increasingly apparent that these chemicals have patterns of non-linear response."

An 'urgent review' of pesticide licensing is needed

Given these concerns, said Holden,

"there is a strong case for an urgent review of the regulatory process for licensing both the herbicide Roundup and the neonicotinoid class of insecticides. A fundamental review of the entire process for licensing agricultural chemicals is required to ensure that in future the public interest is better served."

Professor Pete Myers, Chief Executive of Environmental Health Sciences and scientific advisor to the SFT points out that only "the tiniest fraction of agricultural chemicals" have been studied for health effects by independent scientists:

"Over the last two-decades there has been a revolution in environmental health sciences that suggests the proportion of diseases attributable to chemical exposures is far bigger and more significant than previously understood.

"The tools we have available to us to say what is safe and not safe are deeply flawed. They are not based on two decades of development in the fields of endocrine disruption and epigenetics, but instead on tests developed in the 1950s.

"They do not reflect the complexity of mixtures, or the way in which chemicals interact."

Oliver Tickell edits The Ecologist

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