THE SÉRALINI AFFAIR

A comprehensive review and analysis, by Josh Callan



Introduction

In November of 2012, a paper titled "Long term toxicity of a Roundup herbicide and a Rounduptolerant genetically modified maize" was published in the prestigious Food and Chemical Toxicology yearly journal. In it, the group led by Gilles-Éric Seralini explained a 2-year long study in which Sprague-Dawley rats were fed the genetically modified Monsanto maize crop NK603, as well as the herbicide RoundUp. The corn percentages were 0% (for the controls), 11%, 22% and 33%. A different group was fed the NK603 and RoundUp, administered in their water. Finally, a third group was only fed glyphosate (RoundUp).

- The authors concluded: "The results [...] demonstrate that [...] glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances. Similarly, disruption of biosynthetic pathways that may result from overexpression of the EPSPS transgene in the GM NK603 maize can give rise to comparable pathologies."
- These conclusions were heavily criticized, as was the protocol followed during said experiment.
 Scientists claimed that the conclusions were impossible to justify. Peers also criticized the fact that a book and a movie were released simultaneously with the paper and the fact that those who attended the press conference had to sign a confidentiality agreement.
- After an exhaustive investigation from the EFSA concluded that the paper should be retracted, it
 was so on November of 2013.

Chronology

- NK603 is deregulated after the USDA issues a "finding of no significant impact".
- Monsanto starts commercializing the NK603 trait as "Roundup Ready 2".
- Monsanto publishes the results of a 90 day long feeding trial on rats led by Bruce 6
 Hammond
- The journal "Food and Chemical Toxicology" publishes the paper "Long term toxicity of a Roundu herbicide and a Roundup-tolerant genetically modified maize", written by a team of scientists led by £r Séralini.
- The first criticisms from peers and scientific journalists begin to appear
- The EFSA or European Food Safety Agency publishes its preliminary observations on the French scientist's article, admitting that the "scientific quality of the study is not sufficient".
- Two manifestos come out supporting Séralini and his experiment.
- The journal "Food and Chemical Toxicology" publishes a letter to its editor written by the president of
 the French Society of Toxicologic Pathology Elio Barale-Thomas, pointing out critical mistakes in th
 methodology of the experiment and conflicts of interest by Grallini.
- Wallace Hayes, editor of the journal, asks Séralini to withdraw "motu proprio" his article. Séralini refuses to do so, and the article is retracted.









Why is the experiment flawed?

Flaw	Explanation
Strain of rats used is prone to developing tumors	The authors fail to mention that this strain has a 45-80% tumor incidence in the absence of exogenous factors. If tumors appear before 90 days, the tested compund may be dangerous. It was not the case.
Number of rats used is too small	With only 10 rats per sex and group, the study has no statistical weight. For instance, EPA recommends using 50 rats per sex and group and testing multiple species in a carcinogenicity study.
Unethical treatment of animals and inhuman use of animals for propagandizing	The photographs in the paper show suffering animals that should have been euthanized long before reaching the state they are in. Also, the fact that no whole body photographs of the control animals are shown is a clear misuse of data to present a biased interpretation.
Misinterpretation of data	If the two male groups fed on GM maize are combined, the incidence of early mortality (7/30) is actually lower than that of the control group. References are cited to support the noxious effect of Roundup, but these data were obtained using isolated human hepatocytes, some originating from tumors. The scientific evidence offered by these models is limited by the artificial nature of assays using single cells under non-physiological conditions. Indeed, many compounds that affect such cells have no effect on whole organisms.
Failure to measure the water consumption	This makes it impossible to calculate the real exposure to glyphosate from the concentrations in the drinking water.
Unsubstantiated claims	For example, the authors attribute the potential effects of GM maize and Roundup to endocrine disruption and/or oxidative stress, without any empirical evidence. They also state that GM maize and Roundup can induce necrotic and/or apoptotic changes, but they do not show any evidence to support these statements.
Other	Inadequate statistical analysis of survival and tumor incidence data (e.g. there is no analysis of time to tumor formation). Data presentation deficiencies (e.g. histopathology incidence/severity data not Presented). Low quality and erroneous histopathology analysis (grouping of dissimilar tumor

Academic Capitalism

This expression defines the bilateral dependence between research departments in universities and the private industry: the second provides funding for the carrying out of studies in universities. The first, in return, produce results that are favorable for the company or companies that financed the experiment in the first place.

This phenomenon may also be behind the publication of Séralini's study, since there was more than one company that benefited from it, such as Carrefour and Auchan, in addition to other organizations and individuals.

Monsanto's power structure has close ties with some of the most influential organisms on public health. Not only in the U.S., but also in European organisms. There are several people who are working or have worked for Monsanto that are or were also occupying at the same time a highly influential job on political parties, regulatory bodies or administrative entities. So, for example, William Conlon and Sam Skinner are members of Monsanto's legal team, but also work for the Department of Justice. Michael Kantor is in Monsanto's board of directors, representing it at times as a lawyer, but also occupies a position in the Secretary of Commmerce. Michael A. Friedman is the senior vice president for clinical affairs at G.D. Searle & CO (currently merged with Monsanto) and is an acting commissioner on the FDA. These are just a few of the examples of the people who work both at Monsanto and at an organization closely linked to the development of its practices, at a political, regulatory or advisory level. This could not only help Monsanto achieve faster approval for products that are sought to be introduced in the market, but also perhaps lower the safety standards for their health goods, potentially decreasing the economic cost of their development and speeding its income.

As a conclusion, more long term studies are required in order to properly evaluate and assess the safety of GMOs. A different, perhaps more independent approach is necessary than the one taken in regular risk assessment tests, since these could still be more exhaustive. Academic capitalism must be fought, probably with publicly and not privately funded experiments, to promote more and better communication to the general public and lack of bias.

