What are we to make of the 'Séralini studies' claiming GMOs and glyphosate are dangerous?

<u>Gilles-Eric Séralini</u>, a professor of molecular biology at the University of Caen, is a self-acknowledged critic of GMO crops and herbicides — such as glyphosate — often paired with them.

In 2007, Séralini published a peer-reviewed Greenpeace-funded study that concluded there were health risks with GMO foods. The independent European Food Safety Authority and the French Commission du Génie Biomoléculaire (AFBV) found the study flawed and disputed its conclusions.



In 2009, the Séralini lab published a study concluding that the three corn crops resistant to the herbicide glyphosate caused liver, kidney and heart damage in rats. The French Haut Conseil des biotechnologies (High Council of Biotechnologies Scientific Committee or HCB) reviewed the study and concluded that it "presents no admissible scientific element likely to ascribe any haematological, hepatic or renal toxicity to the three re-analysed GMOs."

A 2011 article by the Séralini lab reviewed 19 published animal-feeding studies, as well as data from animal-feeding studies submitted by industry for regulatory approval, concluding that GMO foods caused

liver and kidney effects.

The release in September 2012 of yet another study by Séralini and his team sent shockwaves throughout the scientific community because it was published in a major journal, Food and Chemical Toxicology, and was accompanied by dramatic photos of tumor-afflicted rats. Seralini released a book and film promoting his findings on the day the article appeared, and he and his supporters launched a massive worldwide public relations effort the same day.



The 24-month study, billed by anti-GMO advocacy groups as the first of its kind, centered around the feeding of GMO corn to rats. Researchers reported the development of cancerous tumors, particularly among the female rats. Among the conclusions:

The results of the study presented here clearly demonstrate that lower levels of complete agricultural glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances.

Anti-GMO forces were quick to seize on the study as evidence of the dangers presented by the genetic modification of crops. The results were released as California was in the midst of a GMO labeling ballot initiative that eventually failed. One of the campaign leaders, Gary Ruskin, now of US Right to Know, but then a leader of the California initiative, said:

This new study is destined to raise more questions than it answers. But at this point, a few things are clear. It is outrageous and shocking that this is the first long-term feeding study, even though this genetically engineered corn has been on the market for nearly 20 years.

In fact, by 2012 there were dozens of long-term studies of GMO crops (see <u>here</u> and <u>here</u>) and <u>glyphosate</u> and many more since, with none showing that either GMOs or glyphosate pose serious health risks.

The Séralini study touched off an international furor, widely known as the Séralini Affair. Kenya, an African pioneer in crop biotechnology, issued an indefinite ban on all GM crops, citing the study, and other African

governments slowed research or put it on hold.

Séralini's research was immediately criticized by prominent scientists (as reported <u>here</u> and <u>here</u>), who took issue with its methodology and lack of supporting data. Among the complaints was the choice of rats, a type known for its propensity to develop mammary tumors.

Regulatory agencies around the world reviewed and rejected the study's methodology and conclusions. A joint report by three Canadian <u>regulatory agencies</u> identified "significant shortcomings in the study design, implementation and reporting." Six French national academies (of Agriculture, Medicine, Pharmacy, Science, Technology and Veterinarians) issued a joint statement — a rare event in French science— condemning the study and the journal that published it. Similar conclusions were reached by the French HCB and the French National Agency for Food Safety, the Vlaams Instituut voor Biotechnologie, the Technical University of Denmark, Food Standards Australia New Zealand, the Brazilian National Technical Commission on Biosafety and the European Food Safety Authority.

The EFSA concluded:

The study as reported by Séralini et al. was found to be inadequately designed, analysed and reported...The study as described by Séralini et al. does not allow giving weight to their results and conclusions as published. Conclusions cannot be drawn on the difference in tumour incidence between treatment groups on the basis of the design, the analysis and the results as reported. Taking into consideration Member States' assessments and the authors' answer to critics, EFSA finds that the study as reported by Séralini et al. is of insufficient scientific quality for safety assessments

It was also noted that the French scientist's results were far off from the reality of a world where GMO corn had by then been widely consumed by humans since 1996. In 2014, University of California-Davis Department of Animal Science geneticist <u>Alison Van Eenennaam</u> reviewed 29 years of livestock productivity and health data from both before and after the introduction of genetically engineered animal feed an estimated 100 billion animals. She found no evidence that health issues escalated after 1996.

Globally, food-producing animals consume 70-90 percent of genetically engineered crop biomass, mostly corn and soybean, with not one documented case of health issues or increases in cancer tumors by animals or humans who consume the animals or eat dairy-related products.

No study has revealed any differences in the nutritional profile of animal products derived from GMO-fed animals. Because DNA and protein are normal components of the diet that are digested, there are no detectable or reliably quantifiable traces of GMO components in milk, meat, and eggs following consumption of GMO feed.

In November 2013, after a year of continued public outcry by the science community and pressure from the agricultural biotechnology industry, Elsevier, the publisher of Food and Chemical Toxicology, announced a <u>retraction</u> of the paper. The publisher's editor said he found no evidence of fraud or intentional misrepresentation of data. But wrote:

However, there is a legitimate cause for concern regarding both the number of animals in each study group and the particular strain selected. The low number of animals had been identified as a cause for concern during the initial review process, but the peer review decision ultimately weighed that the work still had merit despite this limitation. 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.

Séralini supporters, including a <u>group of scientists</u> and anti-GMO groups, attacked the retraction, accusing the journal of bowing to pressure from Monsanto. They argued that the journal held the Séralini study to a higher standard than other similarly inconclusive works. The Séralini-led European Network of Scientists for Social and Environmental Responsibility (ENSSER), whose deputy chairman is co-author of the French study and whose membership is a †Who's Who' of anti-biotechnology scientists, <u>released a</u> <u>statement</u> calling the retraction "a severe blow to the credibility and independence of science, indeed a travesty of science. The conclusiveness of their data will be decided by future independent science, not by a secret circle of people."

Claire Robinson, an editor with GM Watch, wrote:

It is important that scientists do not overstate their findings or draw conclusions that are not justified by the data, but Prof Séralini's paper does not do this. Because Prof Séralini's study was a chronic toxicity study and not a full-scale carcinogenicity study, which normally requires larger numbers of rats, he conservatively did not do a statistical analysis of the tumours and mortality findings. Instead he simply reported them, without drawing definitive conclusions. This is in line with the OECD chronic toxicity protocol, which requires that any "lesions" (including tumours) observed are recorded.

A modified version of the retracted paper was <u>republished</u> in June 2014 in Environmental Sciences Europe, a journal that charges researchers to publish their studies. It was not peer reviewed. [An analysis of the study <u>here</u>]. This set off another round of debates, with scientists generally agreeing that the nearly identical republished paper suffered the same flaws as the original. David Vaux, medical researcher at the Walter and Eliza Hall Institute in Australia wrote:

Instead of performing new experiments, in which more control animals were included, the animals were randomised and treated in an unbiased and blinded fashion, the results analysed with robust statistics, and the full dataset provided in the supplementary material, the authors have repackaged the same data as before, but have found a journal with lower standards for publication.

Séralini has continued to publish studies attempting to demonstrate the dangers of GMOs and glyphosate. In 2014, Séralini and his team published a <u>study</u> in BioMed Research International claiming that pesticides were more toxic than regulatory bodies previously thought. The study prompted Ralf Reski, one of the editors of the journal in which it was published, to resign. Reski said, "I do not want to be connected to a journal that provides [Séralini] a forum for such kind of agitation."

Conflict of interest concerns aside, critics took aim at the premise of the study, which is based on the results of his discredited 2012 work. Others criticized the study's controls and challenged the dosages used. Steve Savage, plant pathologist and genetics consultant, told the Genetic Literacy Project in an email:

The dose is absurd. They gave the animals the equivalent of what could be in the spray tank including the surfactants and the a.i. (active ingredients). If glyphosate or its AMPA metabolite ever end up in a food, it is at extremely low concentrations and never with the surfactant. Unless you were a farmer or gardener who routinely drinks from the spray tank over 8 days, this study is meaningless.

A series of longer-term studies commissioned in the wake of Séralini's 2012 rat tumor study have appeared in recent years. In 2014, a <u>European Union-funded 90-day animal feeding study</u> found no evidence to support a link between GMO corn or glyphosate and cancer, <u>conclud</u>ing: "[GMO corn] at a level of up to 33% in the diet did not induce adverse effects in male and female Wistar Han RCC rats."

In July 2015, Séralini was part of a team of researchers that published a <u>study</u> in PLOS One about the presence of toxic levels of environmental contaminants in the commercial diets of laboratory rodents [Analysis of the study <u>here</u>]. They argued that the presence of these pesticides and other contaminants make it difficult to use control groups in animal feeding trials:

Efforts towards safer agricultural practices and better control of environmental contaminants have to be made in order to feed laboratory rodents with healthy diets. This will not only improve the reliability of toxicity tests, but also the value of animal feeding trials in biomedical research.

The findings were rejected by the EFSA:

There are several limitations with the methodological approach used by the authors, including insufficient information about the test material and methodology used, incomplete reporting of the data, and inappropriate interpretation of legislation and results. In conclusion, no new scientific elements were provided that would impact on the validity of regulatory feeding tests in the EU.

Séralini's January 2016 paper purportedly showing that the first commercialized GMO corn in Europe, grown from 1997-2002, was "toxic to animals over the long term" was published in another pay-for-play journal, Scholarly Journal of Agriculture Science. It states that it "was not designed as a scientific experiment," yet it concludes that GMO corn (which is no longer available in the European market) likely played a role in the poor health of dairy cows.

As Séralini's reputation soured over the years, he increasingly has turned to ideological allies to support his research and public speaking projects aimed at attacking biotechnology and the crop protection chemicals used in modern agriculture.

Many of his financial and ideological ties to alternative food, health and farming associations and corporations came to light after the publication of a 2016 <u>paper</u> in an open source journal that purported to demonstrate the protective effects of Digeodren, a homeopathic product made by Sevene Pharma, which <u>pays</u> Séralini to research atrazine and glyphosate risks. His research team included a former director from Sevene.

This study claimed Digeodren can reverse the toxic effects of prolonged exposure to glyphosate. Critics took aim at the premise of the study, which is based on the contested results of Séralini's discredited 2012 research. Others challenged the study's controls and raised questions about the dosages used.

Other alternative medicine, food and farming organizations that have funded Séralini's work include:

- JMG Foundation (formerly the Goldsmith Foundation, led by environmental activist Ben Goldsmith)
- Lea Nature, organic and natural products company
- Foundations Charles Léopold Mayer for the Progress of Humankind
- Nature Vivante, ecological trade association
- Malongo, fair trade, organic coffee company
- Denis Gouchard, natural living foundation
- Rodale Institute, an organic activist nonprofit run by Anthony Rodale whose mission is "To educate the public about the positive health and environmental benefits of organic food and farming."
- The Sustainable Food Alliance, non-profit organization run by Rodale

A 2016 <u>European Union-funded study</u> showed that rats fed glyphosate-tolerant corn for a full year suffered no ill health effects. "The results obtained show that [GMO corn]...in the diet did not induce adverse effects," the study authors wrote.

In December 2018, a group of French <u>researchers also tried to replicate</u> Séralini's 2012 findings that glyphosate paired with genetically modified corn can cause cancerous tumors in rats. They fed rats glyphosate-tolerant corn and monitored their health for six months, but could not replicate Séralini's controversial findings, concluding:

[U]sing this experimental design, no biomarkers of adverse health effect could be attributed to the consumption of GMP [genetically modified plants] diets in comparison with the consumption of [non-GMO plants].

In February 2019, a <u>long-term study</u> funded by the European Union produced no evidence to support Séralini's contentions. This research included a two-year animal feeding trial in which rats were fed GMO corn treated with glyphosate or untreated GMO corn and compared to a control group fed non-GMO corn. The authors found "... no adverse effects related to the feeding of the [GMO corn] cultivated with or without Roundup for up to 2 years."