Republished retracted Séralini GMO corn rat study faces harsh criticism from scientists

The <u>new rat corn study</u> by Gilles-Éric Séralini looks a lot like the old <u>retracted</u> one, according to a detailed analysis by the <u>Genetic Literacy Project</u>. Independent scientists who have reviewed it—unlike the prior study, this was released to scientists for review ahead of time—say it has all of the flaws of the first study that led to sharp criticism from the global mainstream science community.

[NOTE: Click here to read fact profile of Gilles-Éric Séralini]

Last October, the editor of the *Food and Chemical Toxicology*, A. Wallace Hayes, <u>sent the French</u> <u>molecular biologist a letter</u> notifying him that his September 2012 paper—"Long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize"—would be withdrawn. The publisher then <u>formally retracted</u> the paper when Séralini refused to do so voluntarily.

When the retraction was announced, the French scientist, who is a professor at the University of Caen and is founding director of anti-GMO research group called CRIIGEN, the Committee for Research and Independent Information on Genetic Engineering, said the journal's criticisms of his work was "unacceptable," adding, "Were FCT to persist in its decision to retract our study, CRIIGEN would attack with lawyers, including in the United States, to require financial compensation for the huge damage to our group."

Criticism of retraction

Despite the flaws and inconclusive results in the original research, the anti-GMO movement, with Séralini and his pictures of twisted rodents as icons, began pressuring governments to take "precautionary" actions. The French prime minister said that if its results were confirmed, his government would press for a European-wide ban on GMO maize. Russia suspended imports of the corn. Kenya, an African pioneer in GM technology, issued an indefinite ban all GM crops.

Other long-term studies, which were publicly funded, had uncovered no health issues with GMO corn or the herbicide glyphosate. The Japanese Department of Environmental Health and Toxicology released a <u>52-week feeding study</u> of GM soybeans in 2007, finding "no apparent adverse effect in rats." In 2012, a team of scientists at the University of Nottingham School of Biosciences <u>released</u> a review of 12 long-term studies (up to two years) and 12 multi-generational studies (up to 5 generations) of GM foods in the same journal that published the Séralini paper, concluding there is no evidence of health hazards." Consequently, there was growing pressure on the journal to <u>retract the original study</u> since <u>publication</u> in 2012, along with other criticisms and an exchange of letters in the journal.

Hayes finally pulled the paper, writing it was "<u>inconclusive</u>," grounds consistent with Committee on Publication Ethics (COPE) guidelines, although <u>others disagreed</u>, including Ivan Oransky at Retraction Watch. He <u>explained</u> the peer review process, the international criticism the article prompted from the mainstream science community and the subsequent review and reasons behind the decision to retract.

The journal's retraction notice appeared to be carefully crafted, probably in anticipation of a legal response by Séralini, who had brandished the paper and its accompanying pictures of cancer-riddled rodents as 'proof' that genetically modified foods pose potentially serious health hazards, despite scientific evidence to the contrary.

"Unequivocally, the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data." Wallace wrote. "However, there is legitimate cause for concern regarding both the number of animals in each study group and the particular strain selected. ... This retraction comes after a thorough and time-consuming analysis of the published article and the data it reports, along with an investigation into the peer-review behind the article."

Many scientists and journalists believe the journal badly handled the peer review process and the subsequent retraction. It is a black eye for the beleaguered journal and Elsevier, Bruce Chassy, professor emeritus and retired chair at the Department of Food Science at the University of Illinois, told the GLP. "Their motive appeared to be to deny culpability, protect your reputation, and immunize yourself against lawsuits instead of do the right thing. The narrowness of the retraction overlooked many other deficiencies."

The botched handling of the retraction stirred a heated controversy, which was fanned by the anti-GMO community. A website set up to promote the Séralini study, GMO Seralini, released a full blown <u>response</u> by the embattled scientist and his co-authors.

We, authors of the paper published in FCT more than one year ago on the effects of Roundup and a Roundup-tolerant GMO (Séralini et al., 2012), and having answered to critics in the same journal (Séralini et al., 2013), do not accept as scientifically sound the debate on the fact that these papers are inconclusive because of the rat strain or the number of rats used. We maintain our conclusions. We already published some answers to the same critics in your Journal, which have not been answered (Séralini et al., 2013).

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 antibiotechnology scientists, <u>released a 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, editor of the ENSEER site and the anti-GMO activist GM Watch, <u>blasted</u> the retraction announcement as "illicit, unscientific, and unethical." It was the first salvo in a vigorous defense of the study over the past year.

Séralini has not yet sued the journal, but he has now responded in a different way. On June 24, the retracted study, in <u>expanded form</u>, this time including the data, was republished with the tile "Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" in an obscure open source journal, *Environmental Sciences Europe*—where Seralini has published before.

As <u>Retraction Watch</u> reports, ESE, "part of SpringerOpen, is too young to have an official Impact Factor (IF). <u>Using the same calculation</u>, however, the journal would have an IF of .55. That would place it about 190th out of the 210 journals in the "environmental sciences" category at Thomson Scientific. (For comparison, Food and Chemical Toxicology has an IF of just above 3, and a ranking of 27th.)"

This <u>study</u> is almost identical to the prior study, with some minor but important differences. Séralini claimed in a <u>press release</u> that the republished study was peer reviewed but that is <u>not accurate</u>, according to the publishing journal's editor made to Nature magazine. "We were Springer Publishing's first open access journal on the environment, and are a platform for discussion on science and regulation at a European and regional level." *ESEU* conducted no scientific peer review, said editor Henner Hollert, "because this had already been conducted by *Food and Chemical Toxicology*, and had concluded there had been no fraud nor misrepresentation." The role of the three reviewers hired by *ESEU* was to check that there had been no change in the scientific content of the paper, Hollert added.

As before, the study claimed that rats fed a diet containing NK603—a seed variety made tolerant to the spraying of glyphosate (Monsanto's Roundup herbicide)—died earlier than those on a standard diet. The Séralini team reported that 50 percent of males and 70 percent of females died prematurely, compared with only 30 percent and 20 percent in the control group. The number of rats used in the study was too small to draw statistically meaningful conclusions. The study team also selected a breed of rat to use in the experiments in which 80 percent routinely develop cancers, further obscuring the results. Some of the rats fed GM corn outlived the control group, further confusing the picture. The newly-released study, as the first version, did not include any pictures of the control rats. Critical scientists say that is most likely because the type of rat used is tumor prone and would almost certainly show numerous tumors after two years of life; including pictures of control rats with tumors would further undermine Séralini's claims that the cancer was caused by the corn or glyphosate.

At that time, the authors themselves conceded that the study had flaws, noting in a Criigen press release that "the data are inconclusive, due to the rat strain and the number of animals used."

Séralini study redux

The newly published version of the study, which contained no new experimental data, now no longer concedes that the prior findings were inconclusive. In an apparent attempt to deflect criticism, Séralini et al. also state in this new paper that the original study "was not a carcinogenicity study," but his PR site,

GMO Seralini, <u>claims</u> differently. They also claim, "The retraction of the original paper was unjustified, as "Censorship of research into health risks undermines the value and the credibility of science, thus we republish our paper." The retraction, they write, illustrates "a historic example of conflicts of interest in the scientific assessments of products commercialized worldwide."

There are two parts to the peer review process. Journals send out articles to a limited number of scientists for comment. After publication, the gauntlet continues as studies undergo scrutiny from the mainstream science community. It's in this court that the Séralini papers have failed so miserably.

Geneticists and the general science community were first out of the block after the release of the first study with withering critiques, pointing out more than a dozen problems with the original study, replicated in this republication. The London-based <u>Science Media Centre</u>, which assists reporters when major science news breaks, posted an <u>entire page of criticisms</u>, noting its poor design, the use of tumor prone rodents, the lack of standard controls, the small sample size and the selective presentation of data.

"The study appeared to sweep aside all known benchmarks of scientific good practice and, more importantly, to ignore the minimal standards of scientific and ethical conduct in particular concerning the humane treatment of experimental animals," <u>concluded a prominent group of scientists</u> in *Transgenic Review*. Normally, rodents who develop tumors in experiments are humanely euthanized but in this case they were kept alive and the tumors allowed to grow to grotesque size, and then featured in press releases. None of the results depended on the size of their tumors or how long they lived after the tumor appeared. This unethical treatment of animals was a direct violation of accepted research protocol and was by itself grounds for the article being rejected initially or withdrawn.

After carefully reviewing the study, six French national academies (Agriculture, Medicine, Pharmacy, Science, Technology and Veterinarians⁾ issued an extraordinary joint statement condemning it and the journal that published it. The paper was reviewed and refuted by the most prominent independent international science organizations and every food standards agency of note, including French HCB and the National Agency for Food Safety, the Vlaams Instituut voor Biotechnologie, Technical University of Denmark, Food Standards Australia New Zealand, Brazilian National Technical Commission on Biosafety and the European Food Safety Authority (EFSA).

Quoting the EFSA: "The study as reported by Séralini et al. was found to be inadequately designed, analysed and 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."

Scientists weigh in on republication

The <u>Science Media Centre</u> in the UK and the <u>GLP</u> have both collected responses from top scientists on the republished retracted study. Among the highlights:

David Spiegelhalter, Winton professor of the public understanding of risk at the University of Cambridge:

The article still does not appear to have had proper statistical refereeing, and the methods and reporting are obscure. The claimed effects show no dose-response, and so the conclusions rest entirely on a comparison with ten control rats of each sex. This is inadequate. The study needs replicating by a truly independent laboratory using appropriate sample sizes. I agree with the authors that this whole area would benefit from greater transparency of data and improved experimental and statistical methods.

Marcel Kuntz, biologist, director of research at Centre National de la Recherche Scientifique (CNRS, France) and professor at University of Grenoble-Alpes:

The authors reach essentially the same conclusions that were already refuted and they don't take into account the fundamental criticisms addressed to them. Looking specifically at the tumors: The breed of rats used is subject to spontaneous tumor development. To identify a statistically reliable increase in tumors in a group of rats requires a large number of individuals. This re-publication is still deficient on this point.

These tumors were the most spectacular element of the media operation conducted by the authors. It should be noted that they showed photographs of three rats: a rat that used the GMO NK603, another that drank Roundup and a third absorbed both. Unlike the most basic scientific approach, no control rats (which didn't eat GMO or drink herbicide) were shown. These control rats are still not shown in the re-publication.

Bruce Chassy, professor emeritus of food safety and nutritional sciences from the Department of Food Science and Nutrition at the University of Illinois, Urbana-Champaign:

The original Séralini paper was rejected for many reasons (including) the unethical use of animals in experiments which the Committee on Publication Ethics states is a reason for retraction. Séralini now states that the research was not a cancer study. If that is true, then there was no reason not to euthanize animals when tumors were first detectable. There was nothing to gain or learn. This is unethical treatment of animals.

lan Musgrave, senior lecturer in the Faculty of Medicine, School of Medicine Sciences, within the Discipline of Pharmacology at the University of Adelaide:

The major flaws in this study still remain.

1) The wrong controls were used – there should have been a non-GMO control for each level of GMO corn (i.e. there should have been an 11 per cent control for the 11 per cent GMO corn, a 22 per cent control for the 22 per cent GMO corn and 33 per cent standard corn for the 33 per cent GMO corn. As energy content, carbohydrate load and other components of the corn may affect tumour formation, this is a fundamental flaw which invalidates any conclusions.

2) There is no dose response. For a substance to be an attributable cause of cancer, being exposed to more of the substance should result in more cases of cancer this just does not happen in this study.

3) Furthermore, there is no consistent response to any of the measured outcomes that would even hint at a real adverse effect. The GMO corn had no effect on the number of tumours – Roundup even decreased the number of tumours in male rats, as did the combination of roundup and GMO corn in male rats (there was no consistent effect in female rats). High levels of GMO corn and high levels of roundup both reduced spontaneous mortality and pushed back the onset of death in male rats.

This shows that all we are seeing in these results is due to random variation in a poorly controlled experiment. It does not show that GMO corn, or roundup, even at concentrations that no human would ever be exposed to through diet, have no effect on cancer or mortality.

Thomas Lumley, professor from the Department of Statistics, University of Auckland:

I do not think the republication of the Séralini paper and the responses to critics answer any of the statistical concerns I had with the original paper. The main point of the response over sample size is to argue that some standard toxicological studies also use small sample sizes, which may be true but would not be relevant. Although I do not find it convincing, I am pleased that the study is being republished. While I think it would have been reasonable to reject the paper initially, I was uncomfortable with a retraction that was not based on any new information or any accusation of wrongdoing, and said so at the time. Since the responses to critics claim that much of the opposition is a smear campaign by people funded by Monsanto and the GM crop industry, I think it is appropriate to point out that I have never received funding from Monsanto or any company involved in GM crop technology.

More critical reactions at: <u>https://geneticliteracyproject.org/2014/06/24/scientists-react-to-republished-</u> seralini-maize-rat-study/

The GMOSeralini site issued its defense of the new paper, quoting two well known anti-GMO scientists:

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 called the republication "an important demonstration of the resilience of the scientific community". Dr Heinemann continued, "The first publication of these results revealed some of the viciousness that can be unleashed on researchers presenting uncomfortable findings. 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. 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. In time these findings must be verified by repetition or challenged by superior experimentation. In my view, nothing constructive for risk assessment or promotion of GM biotechnology has been achieved by attempting to expunge these data from the public record."

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