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## Scientists Smell A Rat In Fraudulent Genetic Engineering Study

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Last week French microbiologist Gilles-Eric Séralini and several colleagues released the results of a long-term study in which rats were fed genetically engineered (AKA genetically modified, or "GM") corn that contains enhanced resistance to insects and/or the herbicide glyphosate. They took the unprecedented step of pre-releasing the paper to selected media outlets under an embargo on the condition that they sign a non-disclosure agreement. (That prevented the journalists from seeking scientific experts' opinions on the article.) At a carefully orchestrated media event they then announced that their long-term studies found that the rats in experimental groups developed tumors at an alarming rate. Within hours news of their "discovery" echoed around the world. As we say today, the story "went viral."

But there is both more and less to this story than meets the eye.

Who is Professor Séralini and how did he make this shocking discovery which conflicts with decades of research and extensive worldwide use of genetically engineered crops? Whom should non-experts believe? Is there now evidence that suggests that genetically engineered crops are dangerous?

To begin to answer those questions we need to roll the clock back a few months. In a Forbes.com article earlier this year, we speculated that Séralini was less guilty of actually fudging data to get the desired answer than of performing poorly designed experiments and grossly misrepresenting the results. (Séralini has made a specialty of methodologically flawed, irrelevant, uninterpretable — but over-interpreted — experiments intended to demonstrate harm from genetically engineered plants and the herbicide glyphosate in various highly contrived scenarios.)

The experiment we wrote about purported to show toxicity in vitro to a line of cultured embryonic kidney cells exposed to two proteins commonly incorporated into many varieties of corn, soybean and cotton to enhance their insect-resistance. As we discussed, because the experiment was so poorly conceived, any result would have been meaningless.

We were mistaken about Séralini. The experiments reported last week show that he has crossed the line from merely performing and reporting flawed experiments to committing gross scientific misconduct and attempting fraud.

Séralini claimed that his experiments found harmful effects, including a high incidence of tumors, in laboratory rats fed genetically modified corn and/or water spiked with the commonly used herbicide, glyphosate. The treatments lasted for two years.

There is so much wrong with the experimental design that the conclusion is inescapable that the investigators *intended* to get a spurious, preordained result. Here are a few of the criticisms that have been raised by the scientific community:

- the investigators used a strain of rats that were bred to develop tumors as they aged (a detail they failed to disclose). Significantly, mortality rates and tumor incidence in all experimental groups fall within historical norms for this strain of laboratory rats. Therefore, the claim that the genetically engineered corn component of the diet or the herbicide caused the tumors is insupportable.

- Séralini *et al.* argue that the exceedingly long time-frame of their study was necessary to reveal the experimental effects, but animal researchers long ago established that such lengthy studies add no additional meaningful or valid information beyond that which can be collected in shorter times;

- there is no documentation of the rats' food intake, which strongly affects the incidence of tumors in this strain;

- the experiment included 180 rats (9 groups of 20) fed the genetically engineered or herbicidecontaining diets (the "treated rats"), while only 20 rats were fed a standard (control) diet. Both common sense and a rudimentary understanding of statistics tell you that even if there were no actual differences between the groups, the greater numbers of animals in the *pooled* treated groups increases the odds that one of the treated rats would die first (one of the parameters reported in the paper);

the statistical methods employed were unconventional and appeared to be selected specifically in order to give a certain result. Tom Sanders, head of the nutritional sciences research division at King's College London, called the treatment of data "a statistical fishing trip";



 absence of statistical analysis for mortality or tumor incidence. Statistical analysis is a basic requirement of scientific research, and given that the claims of the study allege tumor and mortality effects, the omission of statistical analysis is inexcusable; - the investigators have refused to release all the data from the experiment, which constitutes scientific misconduct;

insufficient information is provided about the source and quality of corn varieties used in the rats' diet (contamination with molds could be a critical factor);

- absence of data concerning liver or kidney histopathology and liver function tests;

- insufficient explanation of the absence of a dose-response relationship between the experimental variables and supposed effects;

- inappropriate, unnecessary suffering of the rats, which should have been euthanized long before the tumors became so huge – an especially egregious ethics violation given that the study is, in any case, worthless.

- the reported results conflict with innumerable experiments conducted by laboratories around the world on both genetically engineered corn and glyphosate, and also with vast real-world experience.

Finally, the authors wrongly claim that they have no conflicts of interest. Séralini is president of the scientific board of a self-described anti-genetic engineering NGO which apparently is hosted by his laboratory; he has a long and sordid history of anti-genetic engineering and anti-agricultural chemicals activism; and his research is funded by two large, "GM-free" French supermarket chains, purveyors of organic and homeopathic products, and perhaps by other undisclosed parties who stand to profit from the smear campaign against genetically engineered foods.

It also deserves mention that the publication of this article represents an abject, egregious failure of peer-review and editorial competence at *Food and Chemical Toxicology*, the journal in which it appeared. The honorable course of action for the journal would be to retract the paper immediately – a point on which the editors have thus far been silent.

An obvious question is why Séralini would publish such obviously shoddy studies. The answer may be that negative headline stories laden with color pictures of rats with grotesque tumors are not easily forgotten even if the studies are fraudulent. Also, it may be hard for the non-expert to ignore the reported differences between control and experimental groups, and many non-experts will probably believe that where there is smoke, there is fire even if there are flaws in the experiment. But scientists understand that if the design, execution, or analysis of a study is fundamentally flawed, any conclusions are disqualified.

There is no question that the publication of Séralini's latest attack on genetically engineered foods was a well-planned and cleverly orchestrated media event. The study was designed to produce exactly the false result that was observed and was deliberately allowed to continue until large, grotesque tumors developed. The conduct of the study, including the treatment of the animals, raises serious ethical concerns and questions of scientific misconduct.

In the past Séralini and other anti-genetic engineering activists have played the media like a fiddle, but this time even journalists usually willing to trade accuracy and integrity for an "if it bleeds, it leads" story were skeptical of Séralini's claims. Maybe we have reached a turning point where the media will finally realize that they have been manipulated for years by expert professional con-men. Not only was there never any plausible scientific reason to believe that genetically engineered crops posed risks any different from other crops, but hundreds of risk-assessment experiments and the vast cultivation and consumption of them during the past 17 years provide a high level of confidence about their safety and usefulness.

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I've had three distinct careers: biomedical scientist; FDA drug regulator; and scholar at Stanford University's Hoover Institution, a think-tank. During the first of these, I worked on various aspects of gene expression and regulation in viruses and mammalian cells. I was the co-discoverer of a critical enzyme in the influenza (flu) virus. While at the FDA, I was the medical reviewer for the first genetically engineered drugs and thus instrumental in the rapid licensing of human insulin and human growth hormone. Thereafter, I was a special assistant to the FDA commissioner and the founding director of the FDA's Office of Biotechnology. Since coming to the Hoover Institution, I have become well known for both contributions to peer-reviewed scholarly journals and for articles and books that make science, medicine, and technology accessible to nonexperts. I have written four books and more than 1,200 articles. I appear regularly on various nationally syndicated radio programs. My most frequent topics include genetic engineering, pharmaceutical development, and the debunking of junk science. I'm intolerant of dishonesty and hypocrisy and expose them at every opportunity.