

Hyped GM maize study faces growing scrutiny

Food-safety bodies slam feeding study that claims increased cancer incidence in rats.

BY DECLAN BUTLER

The storm of scientific criticism over claims that a genetically modified (GM) maize causes severe disease in rats shows no signs of abating.

Gilles-Eric Seralini, a molecular biologist at the University of Caen, France, is under intense pressure to report the full data behind his team's finding that rats fed for two years with Monsanto's glyphosate-resistant NK603 maize (corn) developed many more tumours and died earlier than controls (see *Nature* **489**, 484; 2012). The study, run in collaboration with the Paris-based Committee for Research and Independent Information on Genetic Engineering (CRIIGEN), also found that rats developed tumours when their drinking water was spiked with glyphosate, the herbicide that is used with the GM maize. The findings have had a huge public impact in Europe, empowering those opposed more broadly to GM foods, and leading some politicians to call for tighter regulations or outright bans of the maize.

Last week, the European Food Safety Authority (EFSA) in Parma, Italy, and Germany's Federal Institute for Risk Assessment (BfR) in Berlin both issued initial assessments slamming the paper, bluntly asserting that its conclusions are not supported by the data presented. "The design, reporting and analysis of the study, as outlined in the paper, are inadequate," says the EFSA in a press release, adding that the paper is "of insufficient scientific quality to be considered as valid for risk assessment".

The biggest criticism from both reviews is that Seralini and his team used only ten rats of each sex in their treatment groups. That is a similar number of rats per group to that used in most previous toxicity tests of GM foods, including Missouri-based Monsanto's own tests of NK603 maize. Such regulatory tests monitor rats for 90 days, and guidelines from the Organisation for Economic Co-operation and Development (OECD) state that ten rats of each sex per group over that time span is sufficient because the rats are relatively young. But Seralini's study was over two years — almost a rat's lifespan — and for tests of this duration, the OECD recommends at least 20 rats of each sex

per group for chemical-toxicity studies, and at least 50 for carcinogenicity studies.

Moreover, the study used Sprague-Dawley rats, which both reviews note are prone to developing spontaneous tumours. Data provided to *Nature* by Harlan Laboratories, which supplied the rats in the study, show that only one-third

be replicated by others, but we believe in these results," he says. He agrees that more rats would have boosted his study's statistical power, but says that he did not design the experiment to show differences in tumour incidences, because he was not expecting to find any — no previous tests on GM foods had suggested a cancer risk.

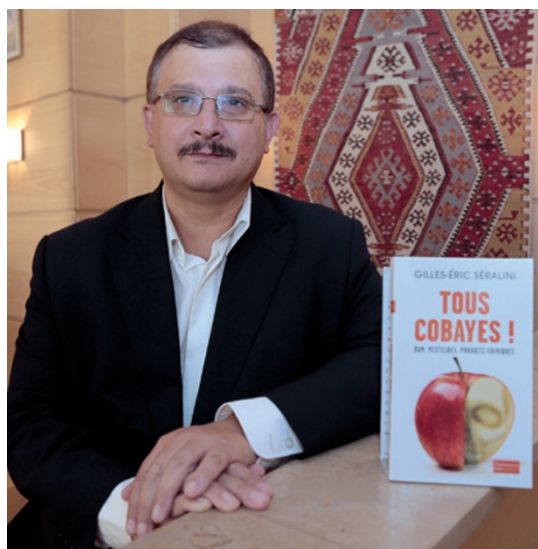
Yet Seralini has promoted the cancer results as the study's major finding, through a tightly orchestrated media offensive that began last month and included the release of a book and a film about the work. Only a select group of journalists (not including *Nature*) was given access to the embargoed paper, and each writer was required to sign a highly unusual confidentiality agreement, seen by *Nature*, which prevented them from discussing the paper with other scientists before the embargo expired.

Journalists often receive embargoed journal articles, and standard practice is to solicit independent assessments before the paper is published. The agreement for this paper, however, did not allow any disclosure and threatened a severe penalty for non-compliance: "A refund of the cost of the study of several million euros would be considered damages if the premature disclosure questioned the release of the study."

In an exceptional move, the ethics committee of the French National Centre for Scientific Research (CNRS) last week decried the public-relations offensive as inappropriate for a high-quality and objective scientific debate, and reminded researchers working on controversial topics of the need to report results responsibly to the public.

Meanwhile, Seralini says that he won't make any data available to the EFSA and the BfR until the EFSA makes public all the data underpinning its 2003 approval of NK603 maize for human consumption and animal feed. He has also criticized the EFSA, and most other detractors of his study, for alleged conflicts of interest, claiming that he is "being attacked in an extremely dishonest fashion by lobbies passing themselves off as the scientific community".

The journal that published his study, *Food and Chemical Toxicology*, said last week in a statement that it "welcomes any and all 'Letters to the Editor' that have questions and concerns about this paper". ■



Gilles-Eric Seralini's book describes his latest GM research.

of males, and less than one-half of females, live to 104 weeks. By comparison, its Han Wistar rats have greater than 70% survival at 104 weeks, and fewer tumours. OECD guidelines state that for two-year experiments, rats should have a survival rate of at least 50% at 104 weeks. If they do not, each treatment group should include even more animals — 65 or more of each sex.

"There is a high probability that the findings in relation to the tumour incidence are due to chance, given the low number of animals and the spontaneous occurrence of tumours in Sprague-Dawley rats," concludes the EFSA report. In response to the EFSA's assessment, the European Federation of Biotechnology — an umbrella body in Barcelona, Spain, that represents biotech researchers, institutes and companies across Europe — called for the study to be retracted, describing its publication as a "dangerous case of failure of the peer-review system".

Seralini argues that a battery of observations in the study reinforces his tumour-incidence and mortality claims. "Of course, this should