

## Scientific publication in peril: the Séralini affair

**Eva Novotny discusses the controversy surrounding an academic paper showing health problems in a feeding trial of a GM crop – and what it says about corporate influence in this field.**

In September 2012 a new study on the potential health effects of a diet containing a herbicide-tolerant genetically modified (GM) crop and/or its associated herbicide was published in a peer-reviewed journal. It provoked a bitter debate. Fourteen months after the publication of the paper, it was retracted by the Editor-in-Chief of the journal because it was “inconclusive” — an unprecedented criterion for retraction. This article recounts the history of the paper, and why many believe that the real reason for its retraction was that the study found evidence of serious health problems resulting from consumption of the GM crop and also of the herbicide, thereby putting Monsanto and the whole GM food and feed industry at risk.

### Two papers: Monsanto vs Seralini *et al*

In 2004, scientists employed by Monsanto had published a paper<sup>1</sup> in the journal *Food and Chemical Toxicology (FCT)* describing a feeding trial of Monsanto's GM maize NK603. “Statistically significant differences” were found in various health parameters between the GM-fed rats and the control rats consuming the same amount of non-GM maize. These differences were deemed by the researchers to be not “biologically meaningful”, and NK603 was declared to be “as safe and nutritious as existing corn hybrids”. The duration of testing was 13 weeks (90 days).

Concerned by the Monsanto paper, a predominantly French team led by Prof Gilles-Eric Séralini undertook a two-year (over 700 days), feeding trial,<sup>2</sup> which was otherwise similar. Their work was published in September 2012, also in FCT. The early warnings that had been dismissed in the Monsanto paper developed into serious illnesses, including damage to liver, kidneys, pituitary gland and, most notably, early deaths and development of large tumours in females. In addition, the study included trials of minute amounts of Monsanto's Roundup, the herbicide to which tolerance has been genetically engineered into NK603, in the rats' drinking water.

### Avalanche of criticism

Immediately after the Séralini *et al* paper was published, pro-GM scientists sent hostile criticisms to

the journal's Editor. The most frequent complaints were that the strain of rat used was wrong and, above all, that not enough rats had been used. The criticisms arose from implicit insistence by the critics that this was a carcinogenicity study, which it was not. At the same time, many other scientists wrote to the journal in support of the paper.

The European Food Safety Authority (EFSA), which had previously approved the maize, was now responsible for passing judgement on a paper that found it harmful. The review<sup>3</sup> concluded that “The study as reported by Séralini *et al* was found to be inadequately designed, analysed and reported.” Many members of the Authority, however, have conflicts of interest with the industries they are meant to regulate.<sup>4</sup>

### A new editor

Some months after the publication of the Seralini paper, a new post of Associate Editor for Biotechnology was created at FCT, and Dr Richard Goodman was appointed to fill it.<sup>5</sup> Dr Goodman was one of the critics who had written to the Editor-in-Chief of FCT to complain about the Séralini paper. He had formerly been employed by Monsanto and has long been involved with the International Life Sciences Institute (ILSI), which is partly funded by Monsanto and other GM seed companies and has a history of influencing governmental risk assessment for the advantage of the funding companies.<sup>6</sup>

A letter<sup>7</sup> initiated by myself and signed for SGR by Philip Webber, Chair, as well as five other scientists and one Research Director, was sent to four staff of FCT and its publisher, Elsevier, urging that the appointment be rescinded. This led to an invitation to nominate a candidate for a new editorial post at FCT to balance Richard Goodman; but, after the retraction of the Séralini paper (see below), no further communication about the post ensued.

Before the arrival of Dr Goodman at FCT, a Brazilian paper also finding potential harm to health from toxins produced in some GM crops was in press and already published by FCT online. Shortly after the arrival of Dr Goodman, the paper was withdrawn. The authors submitted it to another academic journal and it was republished<sup>8</sup> essentially intact.

Richard Goodman is, in fact, not the only editor at FCT with a conflict of interest: several members of the editorial board also have conflicting connections with the GM, chemical or pharmaceutical industries.<sup>9</sup>

### Retraction of Séralini paper — but Monsanto paper stands

Following a second peer review of the Séralini paper, lasting many months and (unusually) examining the raw data, the Editor-in-Chief declared that “Ultimately, the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for Food and Chemical Toxicology.” Thus, on 28 November 2013, over a year after the paper had been published, the Editor-in-Chief retracted<sup>10</sup> the paper on the basis that it was inconclusive — a reason not recognised as valid by the Committee on Publication Ethics (COPE).<sup>11</sup> The paper was considered to be inconclusive because, allegedly, there were too few rats and they were of the wrong type to make the claim that the GM maize and/or Roundup cause cancer. However, no such claim was made; in fact, the word ‘cancer’ never appears in the paper, and not all the tumours were cancerous. The paper was being regarded as a carcinogenicity study, which it was not: the title itself declared it to be a toxicity study.

Prof Séralini and colleagues wrote a detailed ‘Answer to Critics’, later published<sup>12</sup> in FCT, and a Letter-to-the-Editor of FCT<sup>13</sup> on ‘Conclusiveness of toxicity data and double standards’.

Meanwhile, the 2004 Monsanto study remains in publication in FCT despite its very short duration of testing and other faults.

### Independent scientists protest at retraction

Following the retraction, hundreds of scientists and others wrote comments and letters or signed petitions in protest against the irrational and unprecedented retraction.<sup>14</sup> Many scientists committed to a pledge of boycott against publishing their work in the journals of the publisher, Elsevier.

The following extract from a press release<sup>15</sup> by the European Network of Scientists for Social and Environmental Responsibility (ENSSER) conveys the general sentiments of the protests, applicable to all critics and not only EFSA. “EFSA did not apply these same standards retrospectively to the original rat feeding study by Monsanto, ... Use of such double standards is a common response from [pro-GM scientists and government bodies]. Only those studies that find problems are subjected to excessive scrutiny and rejected as defective.”

## Re-publication in another journal

In June 2014, the Seralini et al. paper was re-published with open access in the Springer Group journal *Environmental Sciences Europe*. Again, there was an immediate outcry by GM supporters. In addition, the researchers have published for open access all their raw data — something the GM companies have always refused to do.

## A new paper from the GM industry

The flawed process by which FCT has selected some papers for publication is emphasised by its acceptance of a new study<sup>16</sup> from scientists working in the GM industry. A rat-feeding trial of a GM canola, a type of oilseed rape, by six DuPont scientists found the GM crop to be as safe as non-GM varieties. This conclusion has been challenged by the Seralini team in a Letter-to-the-Editor of FCT,<sup>17</sup> on the grounds that (a) having analysed the diet (obtained from the named company), they found that the diets of the control rats contained large proportions of two GM maize and also glyphosate residue; (b) the usual 3-month duration was too short to show long-term effects; and (c) additional 'control' groups fed 'reference canola varieties' were used. The same strain of rat was used as by the Seralini researchers with 12 rats per sex per group, compared with 10 by the Seralini team. Three rats died or had to be put down during the study. As usual in industry studies, statistical differences were regarded as being "of no biological relevance". The results were said to "support the conclusion" that the canola is safe. To add further insult to injury, the DuPont scientists declared at the end of the paper that they had "no conflicts of interest". Moreover, the lead author is a Managing Editor of the journal.<sup>18</sup>

## Conclusion

The 'Seralini affair' illustrates the pervasive influence and power of major corporations over biotechnology publications and research. Evidence of harm to health caused by products during testing by companies can be hidden under 'commercial confidentiality' or by a poor experimental design. A once-respected journal can no longer be relied upon to be objective, with studies showing harm from GM crops rejected without good reason, while studies finding safety in flawed experiments are published. It is difficult not to conclude that science is being corrupted to suppress legitimate questions about the safety of GM crop technology.

**Dr Eva Novotny has been independently researching issues related to GM crops since 1999. She was a member of SGR's National Co-ordinating Committee from 2001 to 2005.**

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