

# **Oral presentation to the Monsanto Tribunal**

by Claire Robinson, editor, GMWatch

Given the short time available, I'm going to focus on just one topic from my longer written evidence. However, I would like to invite the judges and others who are interested to read the whole of that evidence, in particular the first section on how Monsanto and other GMO developer companies design regulatory systems for their own products, because that's fundamental to the problems that citizens across the world face from the uncontrolled spread of GMOs and their associated pesticides.

I'm going to speak today on how Monsanto and its allies used underhand, deceptive, and non-transparent tactics to try to discredit a scientific study that threatened the company's interests – and to smear the scientists themselves. In this and other similar cases, the company's interests were often represented by third parties such as public relations firms or ostensibly independent academics and scientists (the "third-party" PR technique).

I'm taking as my example a study that has become known as the Séralini study because it represents the most extreme case of malicious and scientifically inaccurate public relations tactics being used to kill an inconvenient study and blacken the names of the researchers. I shall end by describing new followup research that clearly shows that those who attacked the study were unjustifiably putting public health at risk.

I will mention up front that I am not going to claim that the Séralini study is perfect. As I'll explain later, all studies have strengths and weaknesses, and this one is no exception. However, it did not deserve the treatment that it received at the hands of GMO proponents, including Monsanto and its allies.

The study was published in 2012. It was a long-term toxicity study<sup>1</sup> that found that two Monsanto products, a GM herbicide-tolerant maize (NK603) and the Roundup herbicide it was engineered to tolerate, had toxic effects on rats when fed over the long-term period of 2 years. Effects included liver and kidney damage. In addition, a trend of increased tumour rates was found in

<sup>&</sup>lt;sup>1</sup> Séralini et al. RETRACTED: Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food Chem Toxicol. 2012;<u>50(11)</u>:4221-4231. http://www.sciencedirect.com/science/article/pii/S0278691512005637

most treatment groups, although this would have to be confirmed in a dedicated cancer study using larger numbers of animals.

Within hours of the study's publication, a massive PR campaign sprang into operation to try to discredit the study and pressurize the editor of the journal that published it, Food and Chemical Toxicology, to retract it.

The UK-based Science Media Centre (SMC) was in the forefront of the attacks. It collected and disseminated quotes denigrating the study from third-party experts. The SMC defends and promotes GM technology and is 70% funded by corporations,<sup>2</sup> including Monsanto and other big GMO developer firms.<sup>3</sup>

The SMC's director was subsequently <u>reported as saying</u> that she took pride in the fact that the SMC's "emphatic thumbs down" on the study "had largely been acknowledged throughout UK newsrooms". She added that several television news programmes had rejected the story after reading the quotes.

The SMC quotes were also <u>circulated to the media by Monsanto and GMO</u> <u>lobby groups</u>.<sup>4</sup> As a result, the quotes appeared in media coverage worldwide. One <u>popped up in the New York Times</u> along with the scathing comments of Bruce M. Chassy, professor emeritus of food science at the University of Illinois.

At the time, no one could have foreseen that this year, Chassy would be exposed in a media investigation as having received a grant from Monsanto of more than \$57,000 over less than two years. In his promotional activities for GM crops and associated pesticides, Chassy has failed to disclose this relationship with Monsanto and has only described himself by his university role. Indeed Chassy and the University of Illinois directed Monsanto to deposit the payments through the University of Illinois Foundation, a body whose records are shielded from public scrutiny.<sup>5</sup>

### Retraction campaign kicks in

Another key player in whipping up hostility to the Séralini study was the American business magazine Forbes. In the 10 days following the study's

<sup>&</sup>lt;sup>2</sup> Corporate Europe Observatory. Study on Monsanto's GM maize intensifies concerns about EFSA's reliability – Monsanto strikes back with PR offensive. 21 Sept 2012. https://corporateeurope.org/news/study-monsantos-gm-maize-intensifies-concerns-about-efsas-reliability-monsanto-strikes-back-pr
<sup>3</sup> Science Media Centre. Funding. 2012. http://bit.ly/11sRAzV.

<sup>&</sup>lt;sup>4</sup> Corporate Europe Observatory. Study on Monsanto's GM maize intensifies concerns about EFSA's

reliability – Monsanto strikes back with PR offensive. 21 Sept 2012. https://corporateeurope.org/news/studymonsantos-gm-maize-intensifies-concerns-about-efsas-reliability-monsanto-strikes-back-pr <sup>5</sup> Eng M. Why didn't an Illinois professor have to disclose GMO funding? WBez.org, March 15, 2016.

https://www.wbez.org/shows/wbez-news/u-of-i-professor-did-not-disclose-gmo-funding/eb99bdd2-683d-4108-9528-de1375c3e9fb

release, Forbes published 6 attack pieces targeting the research and the researchers. The first two pieces drew on the quotes from the Science Media Centre, but the Forbes piece that grabbed the most attention kicked off with a headline that labelled the paper a fraud. It was written by the American former tobacco lobbyist and defender of GMOs and pesticides, Henry I. Miller, with Bruce Chassy.

The article accused Séralini of "gross scientific misconduct" and of having "a long and sordid history" of "activism". The article concluded by telling the editor of Food and Chemical Toxicology that the only "honorable course of action... would be to retract the paper immediately".

No one could have foreseen that four years later, this September, Séralini was to win a libel case against the French news magazine Marianne and its reporter, who had repeated Henry Miller's allegation of scientific fraud.<sup>6</sup>

But back to the anti-Séralini smear campaign. An <u>online petition</u> was set up, demanding in the name of "the scientific community" that Séralini hand over all his raw data. The petition was aggressively promoted via social media, with <u>the implication that the researchers had something to hide</u>. The assertion that the study was "fraudulent" played well into this campaign, which culminated in Reuters and New Scientist reporting the retraction calls and petition, as well as lacerating comments on the study from UK scientists – provided by the Science Media Centre.

Writing in The Guardian, John Vidal described the attacks on Séralini and his team as "a triumph for the scientific and corporate establishment which has used similar tactics to crush other scientists". These included "Arpad Pusztai of the Rowett Institute in Scotland, who was sacked after his research suggested GM potatoes damaged the stomach lining and immune system of rats, and David Quist and Ignacio Chapela", who found that native Mexican maize had been contaminated by illegally planted GM maize.<sup>7</sup>

In the case of Quist and Chapela, an investigation led by Jonathan Matthews of GMWatch revealed how the campaign of retraction had been carefully orchestrated from the start by Monsanto's PR people. It used proxies to whip up feeling against Chapela by branding him an "activist" rather than a scientist and by maintaining his findings were bogus. GMWatch's research, which was widely reported in the media, suggested that at the heart of the retraction campaign sat Monsanto's former director of corporate communications, Jay Byrne. Byrne had gone on to found his own internet PR

<sup>&</sup>lt;sup>6</sup> GMWatch. Séralini wins defamation case against French news magazine Marianne. GMWatch, 11 September 2016. http://www.gmwatch.org/news/latest-news/17208

<sup>&</sup>lt;sup>7</sup> Quist D, Chapela IH. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature 414:541-543. http://www.ncbi.nlm.nih.gov/pubmed/11734853

company v-Fluence, which is based, like Monsanto, in St Louis.

Although Byrne <u>appeared to be the campaign's chief architect</u>, its principal conduit was the lobby group AgBioWorld, overseen by the GM scientist C.S. Prakash. The <u>"ipetition"</u> attacking Séralini contains no information as to who sponsored it, but its first signatory is C.S. Prakash. Prakash also set up <u>an earlier more primitive version of the petition</u>, which identifies him as its sponsor.

After GMWatch <u>flagged up</u> the likely role of Prakash and AgBioWorld in the ipetition, AgBioWorld acknowledged its authorship <u>in a press release</u>, which asserted that "the petitioning scientists are calling on the publishing journal editors to retract the Séralini study" if Séralini failed to give in to their demand that he hand over all his raw data.

Recently further evidence has come to light,<sup>8</sup> which seems to confirm the extraordinarily close relationship between AgBioWorld and v-Fluence.

The 2012 press release was archived in an early form by the Wayback Machine internet archive in January 2013.<sup>9</sup> On that version of the press release, the source is given as AgBioWorld Foundation. But at the foot of the press release are the words, "All Press Releases By v-Fluence Interactive".

Interestingly though, the press release as it now exists on the PRLog website has had all mention of v-Fluence removed.<sup>10</sup> This suggests a belated attempt to cover up the link between AgBioWorld and v-Fluence. But to us, the facts presented here and in my longer written evidence suggest that AgBioWorld and v-Fluence are interchangeable.

### Outcome of the Séralini study retraction campaign

The retraction campaign against the Séralini study was successful, in that the editor of Food and Chemical Toxicology, A. Wallace Hayes, retracted it after a year of sustained pressure.<sup>11</sup> The retraction followed the appointment of a former Monsanto scientist, Richard E. Goodman, to the journal's editorial

<sup>&</sup>lt;sup>8</sup> http://www.prlog.org/11999640-scientists-call-on-french-researchers-to-release-gmo-test-data.html <sup>9</sup> http://web.archive.org/web/20130124131751/http://www.prlog.org/11999640-sci entists-call-on-french-researchers-to-release-gmo-test-data.html

<sup>&</sup>lt;sup>10</sup> <u>https://www.prlog.org/11999640-scientists-call-on-french-researchers-to-release-gmo-</u>test-data.html

<sup>&</sup>lt;sup>11</sup> Elsevier. Elsevier announces article retraction from Journal Food and Chemical Toxicology. 2013. Available at: http://www.elsevier.com/about/press-releases/research-and-journals/elsevier-announcesarticle-retraction-from-journal-food-and-chemical-toxicology#sthash.VfY74Y24.dpuf. Also see Hayes AW. Letter to Professor GE Séralini. 2013. http://www.gmwatch.org/files/Letter\_AWHayes\_GES.pdf.

## Goodman asks Monsanto to provide criticisms of the Séralini study

A recent investigation by the French newspaper Le Monde<sup>13</sup> uncovered a close collaboration between Goodman and Monsanto. In September 2012, when the Séralini study was published, Goodman was not yet a member of the editorial board of FCT. On 19 September, Goodman informed his Monsanto correspondent about the publication of Séralini's article and said he "would appreciate" it if the firm could provide him with criticisms. "We're reviewing the paper," the Monsanto correspondent replied. "I will send you the arguments that we have developed." A few days later, Goodman was named "associate editor" of FCT, on the decision of the editor, A. Wallace Hayes.

The Le Monde article notes that the addition of Goodman on the editorial board of the magazine was a direct and immediate consequence of the Séralini publication. In November 2012, when the "Séralini affair" was in full flow, the editor Hayes announced in an email to Monsanto employees that Goodman would from now on be in charge of biotechnology at the journal. Hayes added: "My request, as editor, and from Professor Goodman, is that those of you who are highly critical of the recent paper by Séralini and his co-authors volunteer as potential reviewers."

In other words, Hayes was formally inviting Monsanto toxicologists to appraise for acceptance or rejection the studies on GMOs that are submitted to the journal for review.

### Scientific response to the Séralini study retraction

In a series of articles and petitions, hundreds of scientists worldwide condemned the retraction of the Séralini study as an "act of scientific censorship" and as unjustified on scientific and ethical grounds.<sup>14</sup>

<sup>&</sup>lt;sup>12</sup> Robinson C, Latham J. The Goodman affair: Monsanto targets the heart of science. Independent Science News. 20 May 2013. https://www.independentsciencenews.org/science-media/the-goodman-affair-monsanto-targets-the-heart-of-science/

<sup>&</sup>lt;sup>13</sup> Reported in Robinson C. Emails reveal role of Monsanto in Séralini study retraction. GMWatch, 20 July 2016. http://www.gmwatch.org/news/latest-news/17121

<sup>&</sup>lt;sup>14</sup>Heinemann J. Let's give the scientific literature a good clean up. Biosafetycooperative.newsvine.com. 2013. <u>http://bit.ly/1aeULiB</u>; Schubert D. Science study controversy impacts world health. U-T San Diego. January 8, 2014. <u>http://www.utsandiego.com/news/2014/jan/08/science-food-health/</u>; European Network of Scientists for Social and Environmental Responsibility (ENSSER). Journal's retraction of rat feeding paper is a travesty of science and looks like a bow to industry: ENSSER comments on the retraction of the Séralini et al. 2012 study. Berlin, Germany; 2013. <u>http://bit.ly/1cytNa4</u>; AFP. Mexican scientists criticise journal's retraction of study on GMO. terra.cl. December 18, 2013. http://bit.ly/1jVI1HZ; English translation available at: <a href="http://gmwatch.org/index.php/news/archive/2013/15225">http://gmwatch.org/index.php/news/archive/2013/15225</a>; Portier CJ, Goldman LR, Goldstein BD.

In 2014 the Séralini study was republished in another journal, Environmental Sciences Europe,<sup>15</sup> after passing another round of peer review.<sup>16</sup> It remains a citable publication.

#### Was the Séralini study just "bad science"?

Some defenders of GMOs and pesticides argue that these underhand tactics do not matter because ultimately the Séralini study was "bad science" and deserved to be eliminated from the scientific literature.

But this argument does not stand up to analysis. Every study has strengths and limitations, and that includes studies that are claimed to show that GMOs are safe. The strengths of the Séralini study include:

- It was the only study designed to distinguish between effects of the GMO alone, the herbicide it was designed to be grown with, and the two in combination, and
- It tested a large number of toxicological endpoints.

The main limitation of the study is that it used relatively small numbers of rats (10 per sex per group). To put this in perspective, however, this is comparable to, and in some cases superior to, the numbers used in many studies that conclude that the GMO under test is safe.<sup>17</sup>

So if we dismiss the Séralini study because the numbers of rats were too low, we also have to dismiss all these other studies that are used to claim GMO safety.

This number of rats makes the Séralini study too small for a carcinogenicity (cancer) study. So the tumour observations need to be followed up with a dedicated cancer study using larger numbers of rats.

Inconclusive findings: Now you see them, now you don't! Environ Health Perspect. 2014;122(2); EndScienceCensorship.org. Statement: Journal retraction of Séralini GMO study is invalid and an attack on scientific integrity. 2014. <u>http://www.endsciencecensorship.org/en/page/Statement#.UwUSP14vFY4;</u> Antoniou M, Clark EA, Hilbeck A, et al. Reason given for retraction – inconclusiveness – is invalid. 2014. <u>http://www.endsciencecensorship.org/en/page/retraction-reason#.Uweb4l4vFY4;</u> Institute of Science in Society. Open letter on retraction and pledge to boycott Elsevier. 2013. http://www.isis.org.uk/Open\_letter\_to\_FCT\_and\_Elsevier.php#form.

<sup>15</sup> Séralini et al. Republished study: long-term toxicity of a Roundup herbicide and a Rounduptolerantgenetically modified maize. Environmental Sciences Europe. 2014. 26:14.

https://enveurope.springeropen.com/articles/10.1186/s12302-014-0014-5

<sup>16</sup> Robinson C. Was Séralini's republished paper peer-reviewed? GMWatch, 28 June 2014. http://gmwatch.org/index.php/news/archive/2014/15511

<sup>17</sup> Snell C et al. Assessment of the health impact of GM plant diets in long-term
 4 and multigenerational animal feeding trials: A literature review. Food Chem Toxicol 50(3-4):1134-1148.
 2011.

However, the Séralini study was a carefully designed pilot study which offers valuable data to inform followup research.

#### Transcriptomics analysis reflects liver and kidney damage following **Roundup exposure**

One such followup study was published last year.<sup>18</sup> It presents an analysis that reflects the finding of the Séralini study that the lowest dose of Roundup tested – an environmentally relevant dose to which we could all be exposed – caused liver and kidney damage in the rats.

The new study, led by Dr Michael Antoniou of King's College London, focused on analyzing the liver and kidneys from 10 female rats in the Séralini study that had received the lowest dose of Roundup in their drinking water. These were compared with the liver and kidneys of 10 control animals receiving plain drinking water (no Roundup).

This lowest dose resulted in a daily intake that is 75,000 times below the EU acceptable daily intake (ADI) for glyphosate and 437,500 times below the US chronic reference dose (ADI equivalent).

In other words, this dose was far below what is claimed by regulators to be safe to consume on a daily basis over the long term.

Dr Antoniou and colleagues subjected the rats' liver and kidneys to a transcriptomics analysis. This measures the level of expression (function) of all the genes present in the animal. This type of molecular profiling analysis is an established method that is highly predictive of health or disease status of the organ system under investigation.

The analysis showed that over 4,000 genes in the liver and over 4,000 genes in the kidney were either reduced or increased in their expression in the Roundup treatment group, compared with controls, to a highly statistically significant degree.

Of these, a total of over 1,000 gene functions were similarly disturbed in both organs.

The altered gene functions common to both liver and kidney were scrutinized against a database that has been collected over many years and which has

<sup>&</sup>lt;sup>18</sup> Mesnage et al. Transcriptome profile analysis reflects rat liver and kidney damage following chronic ultralow dose Roundup exposure. Environmental Health 2015;14:70.

https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0056-1

correlated gene expression profiles with the health or disease status of a given organ system.

The gene expression changes seen in the new analysis clearly reflect the liver and kidney pathologies found in the Séralini study.

More precisely, the alterations in gene expression profile in both liver and kidneys correlated with disease states such as fibrosis (scarring), necrosis (areas of dead tissue), phospholipidosis (disturbed fat metabolism), and damage to mitochondria (the centres of respiration in cells).

It is important to bear in mind that transcriptomics cannot predict disease or health states with absolute certainty, as not all changes in gene function result in changes in levels of the genes' protein products and metabolites. So although transcriptomics is highly predictive, it does not provide definitive proof of the implied corresponding disease status. Such proof has to be provided by additional molecular profiling analyses that measure the organ's composition, so they are able to provide a direct indicator of the health or disease status of the organ in question.

Dr Antoniou has told me that these followup analyses of the same liver and kidney tissues are under way.

Nevertheless, the results from the transcriptomics analysis show that an ultralow dose of Roundup thousands of times below regulatory permitted daily intake levels can be toxic when consumed on a long-term basis. The fact that such a low dose was toxic suggests that Roundup may be an endocrine disruptor, a class of chemicals that can have toxic effects even at very low doses.

These results call into question the regulatory safety limits set for glyphosate and the claims of safety for glyphosate herbicides on Monsanto's website.

Even though this analysis is as yet incomplete, it clearly shows that valuable data were provided by the Séralini study. The Séralini study and Dr Antoniou's followup investigation have major implications for public health, since biomonitoring studies of glyphosate residues in humans<sup>19</sup> suggest a body burden of this pesticide that is higher than that found to be toxic over the long term in these two studies.

Based on these data, it can be concluded that lobbyists and public relations operatives, including Monsanto-connected ones, should not have attempted

<sup>&</sup>lt;sup>19</sup> Niemann L et al. A critical review of glyphosate findings in human urine samples and comparison with the exposure of operators and consumers. Journal für Verbraucherschutz und Lebensmittelsicherheit. March 2015;10(1):3–12.

to discredit the Séralini study. Their deceptive and non-transparent actions aimed to shut down a line of investigation that could potentially prevent thousands or millions of cases of disease and deaths. Apparently their actions were motivated by a desire to protect commercial interests, with consequent serious risks to human and animal health and the environment.