

Seralini and Science: an Open Letter

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(Authors listed below)

A new paper by the French group of Gilles-Eric Seralini describes harmful effects on rats fed diets containing genetically modified maize (variety NK603), with and without the herbicide Roundup, as well as Roundup alone. This peer-reviewed study (Seralini et al., 2012 [1]), has been criticized by some scientists whose views have been widely reported in the popular press (Carmen, 2012; Mestel, 2012; Revkin, 2012; Worstall, 2012). Seralini et al. (2012) extends the work of other studies demonstrating toxicity and/or endocrine-based impacts of Roundup (Gaivo et al., 2012; Kelly et al., 2010; Paganelli et al., 2010; Romano et al., 2012), as reviewed by Antoniou et al. (2010).

The Seralini publication, and resultant media attention, raise the profile of fundamental challenges faced by science in a world increasingly dominated by corporate influence. These challenges are important for all of science but are rarely discussed in scientific venues. [2]

1) History of Attacks on Risk-finding Studies. Seralini and colleagues are just the latest in a series of researchers whose findings have triggered orchestrated campaigns of harassment. Examples from just the last few years include Ignacio Chapela, a then untenured Assistant Professor at Berkeley, whose paper on GM contamination of maize in Mexico (Quist and Chapela, 2001) sparked an intensive internet-based campaign to discredit him. This campaign was reportedly masterminded by the Bivings Group, a public relations firm specializing in viral marketing and frequently hired by Monsanto (Delborne, 2008).

The distinguished career of biochemist Arpad Pusztai, came to an effective end when he attempted to report his contradictory findings on GM potatoes (Ewen and Pusztai, 1999a). Everything from a gag order, forced retirement, seizure of data, and harassment by the British Royal Society were used to forestall his continued research (Ewen and Pusztai, 1999b; Laidlaw, 2003). Even threats of physical violence have been used, most recently against Andres Carrasco, Professor of Molecular Embryology at the University of Buenos Aires, whose research (Paganelli et al. 2010) identified health risks from glyphosate, the active ingredient in Roundup (Amnesty International, 2010).

It was no surprise therefore, that when in 2009, 26 corn entomologists took the unprecedented step of writing directly to the US EPA to complain about industry control of access to GM crops for research, the letter was sent anonymously (Pollack, 2009).

2) The Role of the Science Media. An important but often unnoticed aspect of this intimidation is that it frequently occurs in concert with the science media (Ermakova, 2007; Heinemann and Traavik, 2007; Latham and Wilson, 2007). Reporting of the Seralini paper in arguably the most prestigious segments of the science media: Science, the New York Times, New Scientist, and the Washington Post uniformly failed to “balance” criticism of the research, with even minimal coverage of support for the Seralini paper (Carmen, 2012; Enserink, 2012; MacKenzie, 2012; Pollack, 2012). Nevertheless, less well-resourced media outlets, such as the UK Daily Mail appeared to have no trouble finding a positive scientific opinion on the same study (Poulter, 2012).

3) Misleading Media Reporting. A key pattern with risk-finding studies is that the criticisms voiced in the media are often red herrings, misleading, or untruthful. Thus, the use of common methodologies was portrayed as indicative of shoddy science when used by Seralini et al. (2012) but not when used by industry (see refs above and Science Media Centre, 2012). The use of red herring arguments appears intended to sow doubt and confusion among non-experts. For example, Tom Sanders of Kings College, London was quoted as saying: “This strain of rat is very prone to mammary tumors particularly when food intake is not restricted” (Hirschler and Kelland, 2012). He failed to point out, or was unaware, that most industry feeding studies have used Sprague-Dawley rats (e.g. Hammond et al., 1996, 2004, 2006; MacKenzie et al., 2007). In these and other industry studies (e.g. Malley et al. 2007), feed intake was unrestricted. Sanders’s comments are important because they were widely quoted and because they were part of an orchestrated response to the Seralini study by the Science Media Centre of the British Royal Institution. The Science Media Centre has a long history of quelling GMO controversies and its funders include numerous companies that produce GMOs and pesticides.

4) Regulator Culpability. In our view a large part of the ultimate fault for this controversy lies with regulators. Regulators, such as EFSA (the European Food Safety Authority) in Europe and the EPA (Environmental Protection Agency) and FDA (Food and Drug Administration) in the US, have enshrined protocols with little or no potential to detect adverse consequences of GMOs (Schubert, 2002; Freese and Schubert, 2004; Pelletier, 2005).

GMOs are required to undergo few experiments, few endpoints are examined, and tests are solely conducted by the applicant or their agents. Moreover, current regulatory protocols are simplistic and assumptions-based (RSC, 2001), which by design, will miss most gene expression changes apart from the target trait-induced by the process of transgene insertion (Heinemann et al., 2011; Schubert, 2002).

Puztai (2001) and others have consequently argued that well-conducted feeding trials are one of the best ways of detecting such unpredictable changes. Yet feeding trials are not mandatory for regulatory approval, and the scientific credibility of those which have been published to date has been challenged (Domingo, 2007; Puztai et al., 2003; Spiroux de Vendmois et al., 2009). For example, Snell et al. (2012), who assessed the quality of 12 long term (>96 days) and 12 multigenerational studies, concluded: “The studies reviewed here are often linked to an

inadequate experimental design that has detrimental effects on statistical analysis ‘the major insufficiencies not only include lack of use of near isogenic lines but also statistical power underestimation [and], absence of repetitions.’”

Apparently, the same issues of experimental design and analysis raised about this (Seralini) risk-finding study were not of concern to critics when the studies did not identify risk, resulting in ill-informed decision-makers. In the end, it is a major problem for science and society when current regulatory protocols approve GMO crops based on little to no useful data upon which to assess safety.

5) Science and Politics. Governments have become habituated to using science as a political football. For example, in a study conducted by the Royal Society of Canada at the request of the Canadian government, numerous weaknesses of GM regulation in Canada were identified (RSC, 2001). The failure of the Canadian government to meaningfully respond to the many recommended changes was detailed by Andree (2006). Similarly, the expert recommendations of the international IAASTD [3] report, produced by 400 researchers over 6 years, that GMOs are unsuited to the task of advancing global agriculture have been resolutely ignored by policymakers. Thus, while proclaiming evidence-based decision-making, governments frequently use science solely when it suits them.

6) Conclusion: When those with a vested interest attempt to sow unreasonable doubt around inconvenient results, or when governments exploit political opportunities by picking and choosing from scientific evidence, they jeopardize public confidence in scientific methods and institutions, and also put their own citizenry at risk. Safety testing, science-based regulation, and the scientific process itself, depend crucially on widespread trust in a body of scientists devoted to the public interest and professional integrity. If instead, the starting point of a scientific product assessment is an approval process rigged in favour of the applicant, backed up by systematic suppression of independent scientists working in the public interest, then there can never be an honest, rational or scientific debate.

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Footnotes

(1) In addition, US scientists who publish studies finding adverse environmental effects are frequently vehemently attacked by other pro-GM scientists. As a report in *Nature*, which discusses numerous examples, points out, “Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists. Behind the attacks are scientists who are determined to prevent papers they deem to have scientific flaws from influencing policy-makers. When a paper comes out in which they see problems, they react quickly, criticize the work in public forums, write rebuttal letters, and send them to policy-makers, funding agencies and journal editors” (pg. 27 in Waltz, 2009a [4]). Indeed, when one of us wrote a Commentary in *Nature Biotechnology* ten years ago suggesting that more attention needs to be paid to the potential unintended effects associated with insertional mutagenesis, we received a flood of responses, and an administrator at the Salk Institute even said that the publication “was jeopardizing funding for his institution” (see Waltz, 2009a). Similar attacks have greeted studies on adverse effects of Bt toxins on ladybird beetles and green lacewing larvae, which were used by German authorities to ban cultivation of Mon810, a Bt corn variety (see: Hilbeck et al. 2012a,b, respectively). In 2009, a group of 26 public sector corn entomologists sent a letter to the US Environmental Protection Agency which stated “No truly independent research can be legally conducted on many critical questions involving these crops [because of company-imposed restrictions]” (pg. 880 in Waltz, 2009b [5]); it was no surprise that the letter was sent anonymously as the scientists feared retribution from the companies that funded their work (Pollack, 2009). Furthermore, industry control over what research can be conducted in the US means that adverse findings can effectively be suppressed. In one example cited in the article, Pioneer was developing a binary Bt toxin, Cry34Ab1/Cry35Ab1, against the corn rootworm. In 2001, Pioneer contracted with some university laboratories to test for unintended effects on a lady beetle. The laboratories found that 100% of the lady beetles died after eight days of feeding. Pioneer forbade the researchers from publicizing the data. Two years later Pioneer received approval for a Bt corn variety with Cry34Ab1/Cry35Ab1 and submitted studies showing that lady beetles fed the toxin for only 7 days were not harmed. The scientists were not allowed to redo the study after the crop was commercialized (Waltz, 2009b). In another example, Dow AgroSciences threatened a researcher with legal action if he published information he had received from US EPA. As the article notes, “The information concerned an insect-resistant variety of maize known as TC1507, made by Dow and Pioneer. The companies

suspended sales of TC1507 in Puerto Rico after discovering in 2006 that an army worm had developed resistance to it. Tabashnik was able to review the report the companies filed with the EPA by submitting a Freedom of Information Act request. "I encouraged an employee of the company [Dow] to publish the data and mentioned that, alternatively, I could cite the data," says Tabashnik. "He told me that if I cited the information I would be subject to legal action by the company," he says. "These kinds of statements are chilling" (pg. 882 in Waltz, 2009b).

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