



## How EFSA dealt with French GM study: which lessons ?

### Summary

The biotech industry has launched an extensive offensive to discredit the study published last September by a team of French researchers suggesting serious concerns about the long term health impact of Monsanto's NK603 maize and the Round-up herbicide it has been genetically engineered to tolerate. As a result, it has been difficult to sort legitimate criticism of the study from industry spin.

Putting this criticism to oneside, the way the European Food Safety Authority (EFSA) has managed the Séralini case does not meet the standards that should be expected from the “keystone of European Union (EU) risk assessment regarding food and feed safety”. Instead of meaningfully contributing to the public debate by sorting the bad arguments from the good, and, more crucially, instead of siding with public safety by calling for more research, EFSA fanned the flames of public controversy by publishing a radically one-sided assessment putting the entire blame on Séralini, applying a level of scientific standards never reached by the Monsanto study on NK603 it accepted for its EU authorisation and ignoring some national agencies' calls to more research and a review of GMOs and pesticides' risk assessment guidelines.

What is more, EFSA failed to properly and transparently appoint a panel of scientists beyond any suspicion of conflict of interests; and it failed to appreciate that meeting with Europe's largest biotech industry lobby group to discuss GMO risk assessment guidelines in the very middle of a EU review undermines its credibility. Today more than ever, EFSA appears to be in need of radical change to become genuinely independent from the industry it is meant to regulate.

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## Introduction

The safety of GM food and Monsanto's herbicide Roundup has once more been put into question following the study published on 19 September in the US scientific journal *Food and Chemical Toxicology* assessing the toxicity of Monsanto's GM (Roundup-tolerant) maize NK603, Roundup herbicide and the two combined, on rats<sup>1</sup>. The study by French scientist Gilles-Eric Séralini immediately hit the headlines around the world. The researchers set out to reproduce a 2004 Monsanto study published in the same journal<sup>2</sup> and used by the European Food Safety Authority (EFSA) for its 2009 positive evaluation of NK603<sup>3</sup>, basing their experiment on the same protocol<sup>4</sup> as the Monsanto study but testing more parameters more frequently, and the rats were studied for much longer (life-time instead of 90 days in the Monsanto study). Industry responded in fury.

### 1. Industry's fight to dismiss a major threat to its business

Published after a four-months peer-review process and two years of research in absolute secrecy to avoid industry pressure, the study's findings were shocking, showing damage to the rats' organs, including the kidneys and liver, as well as severe carcinogenic effects – appalling pictures of rats with large tumours published by the researchers appeared in countless media reports. Industry immediately launched a counter-offensive, seeking to create an image of widespread and heated controversy in the scientific community about this research – even though no serious scientist would normally judge the findings of such a research within hours of its publication.

#### **Methodological debates on GM crops risk assessment: the art of not finding undesired evidence**

Behind this study stands a crucial debate that has been raging ever since GM crops appeared: which methodology to choose to assess toxicity. Nowadays, most food safety regulatory agencies rely on a comparative approach based on the “substantial equivalence” principle, developed in 1991 by the OECD for all novel foods<sup>5</sup>, a concept that was strongly favoured by industry. This principle is a “framework for thinking” according to which a GM crop can be spared extensive safety testing if it is shown that its composition is “equivalent” to its non-GM counterpart when looking at a limited number of nutritional components. EFSA refers to this principle as a “comparative safety assessment”.

This principle has been strongly criticised by scientists for many reasons, mainly because it is undefined, and because it appears to have been designed to spare the biotech industry long and costly safety tests<sup>6</sup>. Critics of GM crops point to the fact that only selected parameters are assessed

1 *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*. Gilles-Eric Séralini, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin, Joël Spiroux de Vendômois - *Food and Chemical Toxicology*,  
<http://www.sciencedirect.com/science/article/pii/S0278691512005637>

2 *Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn*. Hammond, B., Dudek, R., Lemen, J., Nemeth, M., 2004. *Food Chem. Toxicol.* 42, 1003–1014.

3 *Scientific Opinion - Applications (references EFSA-GMO-NL-2005-22, EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto Scientific Opinion of the Panel on Genetically Modified Organisms (Questions No EFSA-Q-2005-249, No EFSA-Q-2008-075) Adopted on 27 May 2009*, EFSA, *The EFSA Journal* (2009) 1137, 1-50, <http://www.efsa.europa.eu/en/efsajournal/doc/1137.pdf>

4 OECD guideline 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents

5 A novel food is “a type of food that does not have a significant history of consumption or is produced by a method that has not previously been used for food.” (Wikipedia)

and for too short a time in these studies, which could mean that any unpredicted or long-term effects are not detected. Nearly all GM plants grown today are, like NK603 maize, 'pesticides plants' (either producing one or several pesticides and/or being genetically modified to tolerate one or several pesticides). Critics say that GM crops should therefore be assessed using a much more robust toxicology protocol. The fact that this study looked at these rats over their lifetime instead of the industry-favoured three months must therefore be seen as an important and welcome attempt to fill a knowledge gap in the risk assessment of GM crops. An attempt which, it should be acknowledged, came at a cost of €3 million, some of which came from supermarkets concerned about the risk of possible future public health scandals.

The counter-offensive drew on critical reactions from individual pro-GM scientists which were promoted to the media via industry-funded groups such as the London-based Science Media Center<sup>7</sup>. Contacts in the media and academia then further dismissed the study in the public debate. Since the study's results were so shocking, countless journalists, bloggers and individuals all over the world took up the controversy and after a few days the tone had generally turned very critical, even though 120 scientists signed a petition in support of Séralini's work and called for more studies on the issue<sup>8</sup>.

This counter-offensive was made easier by the following:

- the study's findings suggested severe public health consequences for products already authorised in the EU for use in food and feed (not cultivation), putting all officials and scientists involved in these authorisations in a very delicate situation – particularly at EFSA where over half of the scientists involved in the GMO panel which positively reviewed the Monsanto's study, leading to its EU-wide authorisation, had conflicts of interests with the biotech industry<sup>9</sup>.
- “extraordinary findings require extraordinary evidence”, and it became clear, after a couple of days of worldwide scrutiny and debate, that the statistical power of the experiment was insufficient for the evidence collected to back all of the study's toxicity and mortality conclusions. Séralini acknowledged later that a minimum of 50 rats per group would have been needed, also meaning the cost of the experiment would have been much higher.
- the PR strategy used by the researchers and their funders, French biotechnology watchdog CRIIGEN, aimed at maximum media impact. The study's media outreach was tightly organised with a film and two books accompanying it, but the confidentiality agreement that journalists had to sign to get the paper in advance of its publication prevented them from

6 *“The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its ‘substance’ ceases to be acceptably ‘equivalent’ is not defined anywhere, nor has an exact definition been agreed by legislators. It is exactly this vagueness that makes the concept useful to industry but unacceptable to the consumer [...] Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests.”*

Millstone E, Brunner E, Mayer S. *Beyond “substantial equivalence”*. Nature. 1999; 401(6753): 525–526, quoted in *GM Myths & Truths*, 2012, Earth Open Source, <http://earthopensource.org/index.php/2-science-and-regulation/2-1-myth-gm-foods-are-strictly-regulated-for-safety>

7 *Study on Monsanto's GM maize intensifies concerns about EFSA's reliability – Monsanto strikes back with PR offensive*, Corporate Europe Observatory, 21 September 2012 <http://corporateeurope.org/news/study-monsantos-gm-maize-intensifies-concerns-about-efsas-reliability-monsanto-strikes-back-pr>

8 *Séralini and Science: an Open Letter*, Independent Science News, October 2 2012 <http://independentsciencenews.org/health/seralini-and-science-nk603-rat-study-roundup/>

9 *Approving the GM potato: conflicts of interest, flawed science and fierce lobbying*, Corporate Europe Observatory, 7 november 2011 <http://corporateeurope.org/publications/approving-gm-potato-conflicts-interest-flawed-science-and-fierce-lobbying>

sending the paper to other scientists to get their feedback before its publication. This contravened usual practice in scientific journalism and triggered a critical approach from a number of popular scientific magazines (New Scientist, Science, NY Times, Washington Post...) dismissing the study<sup>10 11</sup>.

In a nutshell, there was serious criticism to make against some of the study's conclusions and its publication process. But many arguments used by critics either missed the point or were plainly misleading<sup>12</sup>. One of the most blatant flaws was the failure to recognise that most of the criticism targeted at the Séralini study was also applicable to the Monsanto study – and to most studies used for GM crop approval around the world. The industry now appears to be trying to entirely discredit the study by getting the Food and Chemical Toxicology journal to withdraw it, bombarding the journal with critical letters and petitions<sup>13</sup>. This attack is being coordinated by a US-based organisation called AgBioWorld<sup>14</sup>, whose members are linked to conservative think tanks such as the Hoover Institute and the Competitive Enterprise Institute, and which was already involved in the attacks against the US scientist Ignacio Chapela back in 2002 on behalf of Monsanto<sup>15</sup>. AgBioWorld also works in a similar fashion to the Science Media Center by providing pro-GM scientists as media spokespeople<sup>16</sup>.

As a consequence, sorting genuine and legitimate criticism of the study from industry spin has been very difficult. Insightful comments on this were published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER), a scientific association which has defended Séralini but also described in detail the study's limitations<sup>17</sup>. A former governmental expert (wishing to remain anonymous) also commented in detail, and nuances, the study on a GM monitoring website<sup>18</sup>, concluding: “*Bottom line, something is going on in this study that cannot be - must not be - swept away. I conclude that GMOs must be assessed for safety using the lifetime of the test organism.*” Séralini and his team themselves responded to all the main criticisms in an open letter published by Food & Chemical Toxicology, confirming that the statistics regarding mortality and tumours were indeed not sufficient in themselves to draw definitive conclusions on these two aspects but insisting that the convergence between the methodologies and the results was simply too striking to ignore. The team also called for additional research<sup>19</sup>.

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10 *Comment informer de façon neutre sur les OGM ?* Le Secret des Sources, France Culture, 20 October 2012, <http://www.franceculture.fr/emission-le-secret-des-sources-comment-informer-de-facon-neutre-sur-les-ogm-2012-10-20>

11 Independent Science News, *op.cit.*

12 *Intentional Disinformation about Séralini et al.* (2012), E. Ann Clark, Canadian Biotechnology Action Network, September 2012. <http://es.cban.ca/content/download/1492/9351/file/Intentional%20Disinformation%20on%20Seralini.pdf>

13 See f.i. *Dr. Séralini - Please release data from your biotech corn study*, ipetitions.com <http://www.ipetitions.com/petition/dr-seralini-please-release-data/>

14 *OGM : la guerre secrète pour décrédibiliser l'étude Séralini*, Rue89, 12 November 2012, <http://blogs.rue89.com/de-interet-conflit/2012/11/12/ogm-la-guerre-secrete-pour-decredibiliser-letude-seralini-228894>

15 *Joint Statement in Support of Scientific Discourse in Mexican GM Maize Scandal*, AgBioWorld, February 2002 <http://www.agbioworld.org/jointstatement.html>

16 See <http://www.agbioworld.org/experts/index.html>

17 *Questionable Biosafety of GMOs, Double Standards and, Once Again, a 'Shooting-the-Messenger' Style Debate*, ENSSER, 5 October 2012, <http://www.ensser.org/democratising-science-decision-making/ensser-comments-on-seralini-study/>

18 *Comment on Séralini findings and stats by former government analyst*, GMwatch, 1 October 2012, <http://gmwatch.org/latest-listing/51-2012/14249>

19 *Answers to critics: Why there is a long term toxicity due to NK603 Roundup-tolerant genetically modified maize and to a Roundup herbicide*, Food and Chemical Toxicology, 9 November 2012, <http://www.sciencedirect.com/science/article/pii/S0278691512008149>

## 2. EFSA's handling of the case

What has EFSA's contribution been to this debate? After all, as its role is to provide reliable risk assessments for GMOs and other products, one could expect it to help advance the public debate. And surely this should be even more the case given how EFSA has been shown repeatedly in the past to be unduly influenced by industry - and to rely exclusively on industry data in its decisions. Numerous conflicts of interests with the food and biotech industry have been reported among EFSA's experts and management<sup>20</sup> and sign-off of EFSA's 2010 budget was delayed for six months by the European Parliament as a result. Could it use the Séralini case to regain some credibility?

The European Commission was quick to announce it would ask EFSA for an opinion on Séralini's study. However, EFSA has previously positively assessed the very substances challenged by the Séralini study and indeed designed the very risk assessment methodology that Séralini is calling into question. This is even more pertinent given that the EU is currently reviewing its GMO risk assessment guidelines, which are based on those written by EFSA.

It should perhaps be noted that Séralini criticised EFSA when his study was published, saying he would oppose any review of his study by any of the people who had been involved in EFSA's assessment of NK603 and Roundup because they would have a "conflict of interests".

EFSA's initial review of Séralini's study, published on 4 October, was drafted by EFSA staff. But acknowledging the study's results would have meant invalidating 10 years of EFSA GMO risk assessment.

There are also concerns that some of the staff may themselves have conflicts of interest. One of the staff members involved, Claudia Paoletti from EFSA's GMO unit, for instance published a paper with pro-biotech industry scientists Harry Kuiper and Marc Fellous, as well as former colleague Suzy Enkens who has since been recruited as a lobbyist by Syngenta<sup>21</sup>. Doubts are impossible to lift as things stand since EFSA refused to disclose the Declarations of Interest of the relevant staff members. More seriously, one of the two scientists involved in the peer-review of EFSA's paper, Andrew Chesson, contributed to EFSA's positive opinion on NK603 in 2003, a conflict of interest denounced by Corinne Lepage MEP<sup>22</sup>. Why EFSA's management chose to include these people in the group instead of selecting external scientists without conflicts of interests on the matter is not known. As a result, Séralini and EFSA are now in total conflict. Séralini has said he will only publish raw data from his study if EFSA publishes data from the industry studies it used on a public website. EFSA has sent the data to Séralini, but has not made it available to the public and Séralini claims it is incomplete.<sup>23</sup>

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20 *Conflicts on the menu*, Corporate Europe Observatory & Earth Open Source, 31 October 2012, <http://corporateeurope.org/publications/conflicts-menu>

21 *GMO risk assessment around the world: Some examples*. Trends in Food Science and Technology Volume 19, Issue SUPPL. 1, November 2008, Pages S66-S74 <http://www.sciencedirect.com/science/article/pii/S0924224408002239>

22 *Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto I* (QUESTION NO EFSA-Q-2003-002), The EFSA Journal (2003) 9, 1-14, <http://www.efsa.europa.eu/en/efsajournal/doc/9.pdf>

23 *L'équipe Séralini accuse l'EFSA de "mauvaise foi"*, Le Monde, 26 October 2012, [http://www.lemonde.fr/planete/article/2012/10/26/l-equipe-seralini-accuse-l-efsa-de-mauvaise-foi\\_1781695\\_3244.html](http://www.lemonde.fr/planete/article/2012/10/26/l-equipe-seralini-accuse-l-efsa-de-mauvaise-foi_1781695_3244.html)

## 2.1 EFSA's initial review

EFSA's initial assessment is entirely critical of Séralini's study, saying it is “*presently unable to regard the authors' conclusions as scientifically sound*”. In contrast, the French food safety agency ANSES and various scientists<sup>24</sup> have recognised that the study's scale and scope were unprecedented and that several observations made in the report strongly deserved more research.

Indeed, this assessment appears to repeat some of the flawed arguments used by the industry to discredit the study:

- it argues that OECD carcinogenicity guidelines were not followed, and that an exhaustive analysis of the tumours was not carried out, yet Séralini's study was a general toxicity study, not designed to analyse carcinogenic impacts. This criticism actually reflects the need to develop Séralini's work further.
- it argues that the strain of rats used are prone to developing tumours, and that a two-year study therefore cannot be trusted as there is too high a likelihood of the tumours occurring naturally. Yet the strain of rats was the same as used in Monsanto's study, so no other strain could have been used. This type of rat also seems to be used for long-term carcinogenic studies<sup>25</sup>, which would suggest that EFSA's criticism could be applied to many more studies, including the original Monsanto study approved by EFSA.
- EFSA also appears to have applied the very same “double standards” approach to the study as the industry, as explored by Testbiotech<sup>26</sup> which said that by “*failing to challenge the scientific standard of studies which do not show adverse health effects from genetically engineered crops, while at the same time attacking studies that indicate evidence of harm, European Union authorities such as EFSA are applying double standards and follow a biased approach. The authorities seem to be influenced by the presumption that genetically engineered plants should be regarded as safe and seem to be using the debate on scientific standards to defend their own opinions.*”

EFSA's conclusion that the Séralini study “does not impact the ongoing re-evaluation of glyphosate” also seems to be odds with the evidence put forward in the research. Séralini tested Roundup in its commercial formulation, that it to say glyphosate combined with its various additives, because he hypothesised that the combination was potentially more toxic than the ingredients assessed separately. In his study, he calls for a review of Roundup, not glyphosate. The logical conclusion from Séralini's study from a public health perspective should be that more studies are needed to assess Roundup itself, not that this has no consequences for the assessment of its individual components.

In a nutshell, EFSA's initial review resembles more a compilation of other's criticisms than an attempt to clarify the issue in the public interest; more like a prosecution than an evaluation.

## 2.2 Meeting biotech lobbyists to discuss GMOs risk assessment – again

Remarkably, some EFSA staff (including Paoletti) involved in the review of Séralini's study were invited in a luxury hotel in Brussels to discuss GMO risk assessments at a conference organised by Europabio, the biotech industry's lobby group in Brussels on 24 October<sup>27</sup>. EFSA was also

24 See f.i. *Lettre à la Rédaction de La Recherche*, A. Lipietz, 8 November 2012

25 ENSSER, *op.cit.*, p.3

26 *The European Food Safety Authority: Using double standards when assessing feeding studies*, Testbiotech, 30 October 2012, [http://www.testbiotech.de/sites/default/files/the%20double%20standards%20of%20EFSA\\_0.pdf](http://www.testbiotech.de/sites/default/files/the%20double%20standards%20of%20EFSA_0.pdf)

27 *Workshop on the Risk Assessment Requirements for GM food and feed with respect to Toxicology and Allergenicity*,

represented by Harry Kuiper, the scientist who chaired EFSA's GMO panel between 2003 and 2012 and whose links with industry have been clearly documented. These are now the subject of an Ombudsman complaint made by Testbiotech and CEO<sup>28</sup>. Suzy Renkens, the former head of EFSA's GMO unit who left to lobby for Syngenta (and who now lobbies for Europabio<sup>29</sup>), was also in the room. On the other hand, EFSA did invite NGOs to discuss GMO risk assessment issues a month later, but... in Parma<sup>30</sup>.

### 2.3 EFSA's final review

Finally published on 28 November, EFSA's final assessment of the study did not change any of its initial assessment, but simply added the assessments carried out by six Member States' food safety agencies. It also replied to some of the points raised in Séralini's open letter published by in Food and Chemical Toxicology. EFSA's concludes:

*“Considering that the study as reported in the Séralini et al. (2012a, 2012b) publications is inadequately designed, analysed and reported and taking into consideration MS assessments, EFSA finds that it is of insufficient scientific quality for safety assessments. Therefore, EFSA concludes that the Séralini et al. study as reported in their publications (2012a, 2012b) does not impact the ongoing re-evaluation of glyphosate. Based on the currently available evidence EFSA does not see a need to reopen the existing safety evaluation of maize NK603 and its related stacks.”*

Again, EFSA has dismissed the study on the grounds that there is insufficient evidence to back the conclusions on mortality and tumours, a point that is shared by all national food safety agencies and indeed partly by the authors themselves. It repeats the misleading argument that the glyphosate assessment is not in question, but fails to address the issue that Roundup, not simply glyphosate, was used in Séralini's study. EFSA uses these findings to dismiss the study entirely. This is in stark contrast with the conclusions of at least two of the national agencies (from France and Belgium) also involved in the study's assessment which took their public health protection role seriously by calling for additional research and a review of current risk assessment guidelines:

- Belgium's WIV-ISP: *“Considering the issues raised by the study (i.e. long term assessment), the Biosafety Council proposes EFSA urgently to study in depth the relevance of the actual guidelines and procedures.”* (Belgium's food safety experts' conclusions are remarkably split, with a minority opinion asking for *“a reassessment of the advice of the BAC on the initial dossiers of the maize NK603, regarding effects on human and animal health, using the same critical analysis that was applied by the BAC's experts to the Séralini et al. study”*).
- France's ANSES: *“ANSES calls for more public funding on the national and European levels for broad-scope studies to consolidate scientific knowledge on insufficiently documented health risks. [...] [ANSES recommends] more research on the potential health effects associated with the long-term consumption of GMOs or long-term exposure to plant protection products. This research should focus in particular on the issue of exposure to GMOs and to residues of associated plant protection preparations.”* (ANSES was the only food safety agency to be given Séralini's raw data on mortality and tumours).

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Europabio, 24 October 2012, Brussels <http://www.europabio.org/agricultural/positions/workshop-risk-assessment-requirements-gm-food-and-feed-respect-toxicology-and>

28 *Independence of EFSA's GMO risk assessment challenged*, Corporate Europe Observatory <http://corporateeurope.org/pressreleases/2012/independence-efsa-gmo-risk-assessment-challenged>

29 *Former EFSA GMO head lobbies EFSA for Europabio*, EU Food Policy, 23 November 2012

30 *EFSA holds sixth annual GMO meeting with NGOs*, 27 November 2012, <http://www.efsa.europa.eu/en/events/event/121127.htm>

## **Conclusions**

The way the European Food Safety Authority (EFSA) has managed the Séralini case does not meet the standards that should be expected from the “keystone of European Union (EU) risk assessment regarding food and feed safety”. Instead of meaningfully contributing to the public debate by sorting the bad arguments from the good, and, more crucially, instead of siding with public safety by calling for more research, EFSA fanned the flames of public controversy by publishing a radically one-sided assessment putting the entire blame on Séralini, applying a level of scientific standards never reached by the Monsanto study on NK603 it accepted for its EU authorisation and ignoring some national agencies' calls to more research and a review of GMOs and pesticides' risk assessment guidelines.

What is more, EFSA failed to properly and transparently appoint a panel of scientists beyond any suspicion of conflict of interests; and it failed to appreciate that meeting with Europe's largest biotech industry lobby group to discuss GMO risk assessment guidelines in the very middle of a EU review undermines its credibility. Today more than ever, EFSA appears to be in need of radical change to become genuinely independent from the industry it is meant to regulate.