PRESS KIT

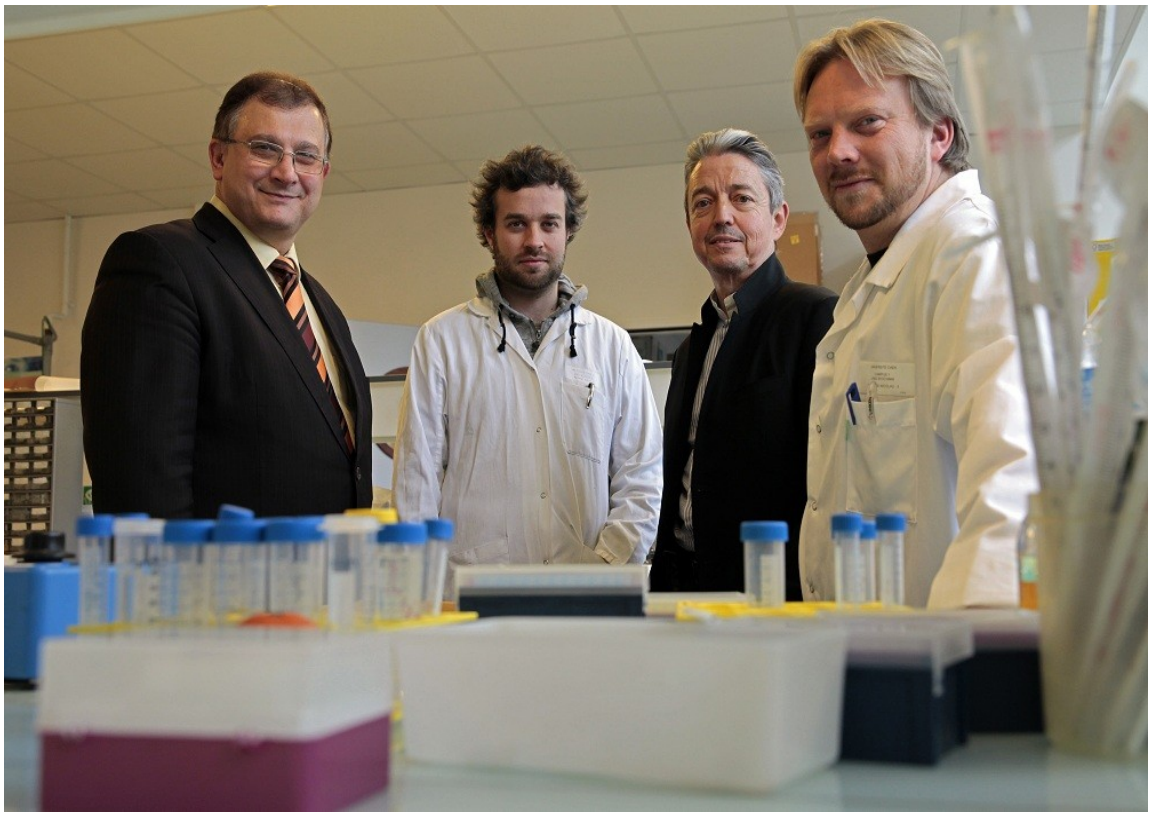
REPUBLICATION OF THE SERALINI et al. STUDY ON THE LONG TERM TOXICITY OF A ROUNDUP HERBICIDE AND A ROUNDUP-TOLERANT GENETICALLY MODIFIED MAIZE

CRIIGEN

Comité de Recherche et d'Information Indépendantes sur le génie Génétique

Press kit provided for the press conference on June 24, 2014 to be held in Paris at 11 am, salle du Bureau du Parlement européen, 288 bvd St Germain with Pr Séralini and the CRIIGEN representatives.

As part of the republication of this study by Professor Séralini's research team we are offering you this detailed press kit:



Part of the CRIIGEN research team, Professor Gilles-Eric Séralini, Dr. Robin Mesnage, Dr. Joël Spiroux de Vendômois (Chairman of CRIIGEN) and Nicolas Defarge.

CHRONIC TOXICITY OF ROUNDUP AND A ROUNDUP-TOLERANT GMO, the main findings

- The main pesticide of the world, Roundup, provokes severe hepatorenal deficiencies and sex-dependent hormonal effects such as mammary tumors from very low environmental levels (0.1 ppb).
- Comparable results have been obtained during chronic consumption of an equilibrated diet containing a Roundup-tolerant GMO (maize). This was due to Roundup residues and to this specific genetic modification (NK603).
- Roundup formulations and Roundup-tolerant GMOs should be considered as endocrine disruptors and their present assessments on health are drastically deficient.

To be kept in mind:

- 80 % of agricultural GMOs are Roundup-tolerant ones. The remaining are Bt-toxins (pesticides) - producing GMOs.
- Roundup does not equal glyphosate, it contains adjuvants more toxic than this declared active principle, like other pesticides.

Chronology: a two-year battle against attempts of censorship

19/09/12	Publication of the paper by Séralini's research team in *Food and Chemical Toxicology* (FCT) for the study of long-term toxicology of a genetically modified NK603 maize and its associated herbicide, Roundup, after acceptance and control by a committee of peer reviewers with a questions and answers phase of 4 months.
04/10/12	EFSA, in coordination with several national agencies, came out with a majorly rushed "pre-notification" concluding that the study was of "insufficient scientific quality to be considered valid for risk assessment" based on the standards of regulatory toxicology (OECD GLP).
10/10/12	Monsanto publishes a comment in the journal FCT criticizing the research. In parallel, a letter writing campaign of attacks and criticisms against Séralini's research team starts in the columns of FCT, written one month before. It was found that more than 75% of published letters were from specialists in plant biology (and not toxicology) and that these specialists held patents or had links with undeclared interests in the biotech industry.
22/10/12	ANSES makes its comments on the study available, recognizing beyond some methodological criticisms, its experimental relevance and the absence of either long-term studies ("chronic") on GMOs, even though they have been on the market since 1996, or on pesticide formulations (active ingredient + adjuvants) *"The Séralini study has the merit of being ambitious and unique, in addressing the issue of long-term effects of GMOs and of residues of phytochemistry products*, observed Dominique Gombert, Head of Risk Assessment of ANSES. *But it has weaknesses and a statistical explanatory order that does not allow to question the previous assessments, nevertheless, it highlights the need to address the issue of chronic risk.*"
09/11/12	Following the criticisms of the study, in a classical scientific process, Séralini's research team sent FCT a point by point response to the criticisms under the 'right of response to criticism' (after acceptance and control by a peer review committee) as well as providing some new scientific evidence from the study, whilst also denouncing the international smear campaign.
02/2013	FCT recruited a new "Associate Editor for Biotechnology", Richard Goodman, a former employee of Monsanto, selling both products (Roundup and GM Maize NK603) and member of the International Life Science Institute (ILSI) (a group of scientific and regulatory lobbyists funded amongst others by the biotechnology industry.)
15/03/13	The Editor of FCT asks Séralini's research team to provide the study's raw data for an exceptional post-publication reassessment by a new committee including Goodman. The team denounces its conflict of interest to the Elsevier publishing group which is the publisher of FCT. Elsevier learns about this situation and asks Goodman to stand down from the committee. But the process continues with Goodman at the editorial board of FCT. The Séralini team plays along with the game even though industry never has to provide their raw data in order to publish their studies concluding on the safety of GMOS.
12/07/13	Taking note of the Séralini study, the *French CGDD* –(Research Department of the General Commission for Sustainable Development) of the Ministry of Ecology issues a call for the

	establishment of a consortium under the research program called Risk'OGM, a French national research program on the environmental and health risks of GMOs. ANSES and INRA responded to the tender but reduced the duration of the study to six months contrary to the expectations of the Ministry. In addition, the European Union picked an inappropriate protocol on cancer.
31/07/13	EFSA issues *"Guiding principles for two-year whole food studies"* including GMOs, thus demonstrating the absence of an experimental protocol formally set out at the time of the publication of the Séralini et al. paper, contrary to criticisms issued by the agency.
19/11/13	The FCT Editor-in-Chief, A. Wallace Hayes, announces a unilateral retraction of the paper without the consent of the authors. He found the paper "*inconclusive*", while recognizing that the raw data verification had found "*no fraud or wilful misinterpretation*" two criteria which are necessary to justify the retraction of a study. Séralini's research team denounced and rejected the retraction at a press conference at the European Parliament a few days later.
30/11/13	Following the retraction of the study, the reporter in the French newspaper Le Monde, Stéphane Foucart, wrote : "*By retracting the article of the French biologist [...] FCT deprives future research of elements of comparison, confrontation and analysis. For inconclusive they are today (which is denied by the authors), nothing says that in the future this data - considered honest by FCT itself - will not be useful or enlightening. The decision of FCT does not seem motivated by the requirements of the science, but rather by the desire to clean the deck - which satisfies the manufacturers concerned.*"
10/12/13	Wallace Hayes wrote an article to defend his position that raises doubts about his understanding of the study and raw data. He mentions in his defense he was unable to conclude that *"there was a clear link between GMO and cancer."* An obvious error of W. Hayes as the term *"cancer"* has never been mentioned in the paper of Séralini's research team. And it does not affect any aspect of the research on Roundup.
01/03/14	Marcel Roberfroid, a former member of the editorial board of FCT, condemned the retraction in a letter in FCT *"Your decision [retraction] can be interpreted as the desire to eliminate scientific information that does not help support industrial interests, which seems unacceptable to me."*
04/03/14	Séralini's research team released a statement about the retraction and some correspondence between the publisher and the *Committee On Publication Ethics* (COPE) which has published recommendations on the conditions for the retraction of papers since 1997. According to the authors, "*the retraction does not meet the ethical requirements set by COPE."* The retraction is neither justified scientifically nor ethically.
18/04/14	FCT publishes a right of response from Séralini's research team with the support of the Journal Publisher Elsevier. Scientists will complain about the fact that the *"Editor-in-Chief of FCT applies double standards regarding publication for the industry. This is a breach of the guarantee of quality and independence of scientific publishing.*"
28/05/14	CRIIGEN, a French research institute, and several French associations leave ANSES 's "dialogue committee" for the Risk'OGM project after the integration of Monsanto's representative and the reduction of the study's duration to 6 months, a far cry from the two years previously suggested by the Department.

Questions and answers about this research and events surrounding its publication

After publication, the study by Professor Séralini et al. had a global impact and put him personally under the media spotlight, but also put him in the target zone of the biotech industry and scientists whose interests were threatened by the team's findings. Through several consecutive articles, the authors responded to the scientific questions and even managed to professionally criticize the impact of conflicts of interest in scientific publishing.

Why a study about the toxicity of the main herbicide in the world, Roundup, and on a Roundup-tolerant genetically modified maize, two of Monsanto's products ?

By launching this unique study, the research team led by Professor Séralini wished **to build on some previous toxicology studies on Roundup and GM maize** published in 2005 & 2007[1]. In 2009, the research team had re-analysed and compared the raw data of the blood and organs of rats fed with GM maize. The raw data came from 90-day-long regulatory studies of Monsanto.

These studies were used as references to place three of Monsanto's genetically modified maize varieties on the market for allowed consumption. The GM maize varieties, MON810 and MON863, as well the NK603 maize made tolerant to the herbicide Roundup were the focus of the study published in 2012. At this time, the results suggested effects on the liver and kidneys, organs of detoxification of the body, as well as biochemical disturbances in rats according to the gender.

The design of the 2-year chronic toxicity study in rodents allowed more time to study the development of the first signs of liver and kidney toxicities. However, if signs of this toxicity had been detected in these 90 day-analyses, they were systematically excluded and "*considered as biologically irrelevant* " by the industry and authorities. By setting up their own study, they could therefore continue the past analyses, maintaining the same standards as the industry, but over an unprecedented period of 2 years. The objective of the toxicological protocol was to check if

1 Richard et al. (2005) Env. Health Perspect. 113: 716-20. (Differential effects of glyphosate and Roundup)

Séralini et al. (2007) Arch. Environ. Contam. Toxicol. 52: 596-602; re-analysis of Monsanto data obtained by the justice on MON863 maize, showing that there may be other sub-interpretations of toxicity for other GMOs.

De Vendomois JS et al. (2009) Int J Biol Sci. 5: 706–26; Reanalysis of toxicological records of Monsanto for 3 GMOs: MON863, MON810 and NK603.

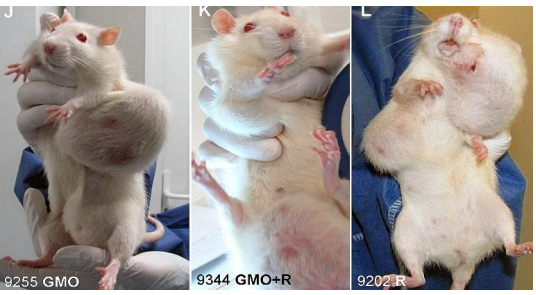
the signals of toxicity were developing into diseases or malfunctions more serious and harmful to health in the long term or over a lifetime.

Moreover, many *in vitro* studies by the team on glyphosate and Roundup showed some toxicity effects (necrosis, apoptosis change, and endocrine disruption). There was more toxicity with the herbicide Roundup that for glyphosate alone, the named "active ingredient" of the herbicide produced by Monsanto. The use of Roundup in its complete formulation was justified as the authorization of pesticides on the market is based solely on an assessment of the so-called “active" molecules and not on the full formulations, which have never been chronically tested.

The study by Séralini et al. has therefore never intended to follow an experimental protocol used in carcinogenicity, even though tumours, which are not all cancers, but that are no less fatal, have been detected.

Why did the study have such a global impact following its publication ?

It is the world's 1st long-term toxicity study with lots of parameters which were measured (blood, body, urinary ...) on the effects of two marketed products. It relates to a full herbicide’s formulation and a GM maize (NK603), and was conducted over a period of two years in rats and in total independence vis-à-vis of the biotechnology industry (here namely Monsanto). The reason for the study having such a global impact is partly because of the unique nature of this study (both in scope, parameters and duration) after a ten-year debate on GMOs, as well as due to the quick photo sharing from the study on media and social networks.



The distribution of photos showing rats with tumours has indeed played a role in the global dissemination without being associated with the actual findings of our study. Most people do not know about toxicology, thus they associate tumours with cancers, which resulted in some of the comments by the press being disconnected from our findings and mixed with vicious attacks from the biotech lobbies.

Furthermore, **this study was challenging the global standards of regulatory toxicology**, demonstrating the limits of 90-day-long GM health studies (or 6 months to 2 years on the active ingredient of pesticides only, nothing on formulations with blood tests) for concluding the non-toxicity of a product and for obtaining a marketing authorization by health regulatory agencies.

Why was it necessary to keep this work secret?

Before its official publication, the study was conducted for two years in secret; several laboratories that participated were ‘blinded’ (for technicians). In addition, these kind of tests must be conducted ‘blinded’ according to international standards. The extraordinary secrecy surrounding this study is due to the significant risk of legal pressure from the agrochemical and agricultural biotechnology corporation Monsanto whose two products, the NK603 maize and Roundup (in a commercialized formulation), were tested independently of them for the first time.

Monsanto has **patents on these products which enable it to restrict any independent research** without prior consent. It is a global phenomenon which has been hindering the research on the assessment of GMOs for years. Knowing this fact, the research team has had to use the utmost discretion to carry out its analyses and to publish the findings, while ensuring that it did not create any pressure on the publisher, which clearly emerged following publication, as well as on the authors before publication.

What responses have been made to the criticisms of the study?

Within 24 hours of the publication of the study, the work began to be subject to criticism and attacks sent to FCT and mainstream press from around twenty scientists, French, English and American, quickly self-proclaimed as the "*international scientific community*". At the centre of this smear campaign was the ***Science Media Centre*** in England, a scientific press office **funded by industry (food, biotech, pharmaceutical**...). Scientists quoted by the *Science Media Centre* or in the French press were actually in most cases plant biologists, holding patents on the technologies criticized, and in other cases they were industry consultants, accounting for 75% of the authors of critical letters which were published by the Editor of *Food and Chemical Toxicology*, despite that none of them have ever published any toxicology research.

The main criticisms were that Séralini’s team used a small number of rats and of a strain which is prone to tumours (Sprague Dawley), and that the OECD carcinogenesis standards were not met. However, the chosen protocol by Séralini’s team was that of a toxicological study over two years and not a protocol for a carcinogenicity study. Meanwhile, numerous toxicological studies use the Sprague Dawley strain, which are not so prone to tumors in appropriate controls, and the studies of Monsanto conducted over three months on its GMOs analyse the same number of rats per group and the same strain. These methodological criticisms were allowed to justify (wrongly) some ‘flaws’ in the protocol while in fact the study complied with the standards of regulatory toxicology (OECD 452 guidelines). The ‘problems’ in statistics concentrated on the number of rats, and standards of the incidence of "normal tumours" of the strain according to Monsanto are artificially high. The statistics used in this study are among the most modern methods.

Why do we challenge the retraction of the study by the Editor Wallace Hayes of *Food and Chemical Toxicology* ?

The team of Professor Séralini has always fully engaged in the necessary scientific debate according to the rules of the academic world. Furthermore, this team of researchers publish the most studies on GMOs and their associated pesticides in the world in peer-reviewed journals. Faced with the criticism of their study, the researchers have published two articles of detailed responses and counter-arguments in the columns of FCT and provided all their raw data for post-publication review.

An exceptional post-publication panel was first led by Richard Goodman, who entered the editorial board of FCT after complaining about the study. He is a Monsanto former employee, a member of the International Life Science Institute (ILSI, a pressure group acting in favour of GMOs that includes the largest global agrochemical companies, including Monsanto) and whose research at the University of Nebraska are also funded by the Biotech industry. It took the involvement of the parent company (Elsevier), which was aware of the serious conflicts of interest of Mr. Goodman in order for him to be pulled off the post-publication review panel, while remaining in his position as the Editor on Biotechnologies at FCT.

The work of Séralini's team therefore went through an exceptional process to which very few studies are subjected especially those coming from the industry. Despite these in-depth analyses in search of any possible error, the editor of FCT was forced to conclude that "no fraud", "no misconduct", "no intentional misrepresentation of data" was detected. However, taking on his personal responsibility, the Editor-in-Chief **A. Wallace Hayes retracted the paper on the 28th of November 2013 based on the fallacy of "inconclusive" results.** The argument is that the publisher could not conclude a link between GMOs and cancer, despite the fact that this word never appears in this publication - the study has never mentioned this word.

After the unilateral retraction of the study, **the team of Professor Séralini published a press release in January 2014 including information from the *Committee On Publication Ethics* (COPE),** which since 1997 has published recommendations on the conditions for retraction of a scientific paper. Under the criteria of COPE, the retraction does not respect scientific or ethical conditions to remove a paper. To date, the **characterisation** of a study as **"***inconclusive***" (refused by the authors) has never been used to justify the withdrawal of research work after publication.** Only the subsequent replication of a study and a scientific discussion on the data obtained can enable progress towards greater certainty.

Authorized to publish a right of reply in the columns of the FCT, **the authors are forced to conclude that the decision was based on "*double standards*"** applied by the Editor-in-Chief. FCT has published two studies (Hammond et al, 2004 and Zhang et al, 2014), measuring the same number of rats of the same strain, without questioning their statistical power and more their results: the safety of the concerned GMO! The recent study by Zhang et al concerns, as the one of Séralini et al, potential

chronic effects of the consumption of GMOs (transgenic rice producing a modified Bt insecticide) and uses beyond the strain and numbers of rats, a protocol with a much smaller number of measured parameters, and sampling frequency.

Professor Séralini commented :

"We are forced to conclude that the decision of the journal FCT is not conditioned by the rigour of the protocol and of the scientific method, but by our results. This case of "double standards" can only be explained by compromises on publications offered to the Biotech industry, in order to force the acceptance of GMOs and Roundup."

Further studies published in February 2014 confirmed the underestimation of the toxicity of commercialised pesticides.

The team of Professor Séralini published the paper "*Major Pesticides Are More Toxic to Human Cells Than Their Declared Active Principles*" in February 2014 in Biomedical Research International. This study showed that out of nine pesticides analysed, eight are much more toxic than what was tested and reported by the producers.

Three herbicides (Roundup, Matin, Starane), three insecticides (Pirimor, Confidor, Polysect) and three fungicides (Maronee, Opus, Eyetak) were studied.

The results show that **commercial formulations of pesticides tested *in vitro* are up to 1000 times more toxic than their "active principles"** alone without the adjuvants in the formulation, until then considered inert and usually kept confidential by industry

Roundup is the most toxic among all herbicides and insecticides tested in this study. The formulations sold to farmers contain the adjuvants which are more toxic than the declared active principles. Fungicides were the most toxic at doses 300-600 times lower than those used in agricultural usages.

"These results suggest that, in the procedures of assessment recommended by health agencies, the toxicity of pesticides is grossly underestimated, likely resulting in erroneous maximum permitted residue limits which are endangering the populations exposed."

Scientists Condemn Retraction of the Séralini GMO Study

Scientists from around the world have united to condemn the retraction of Séralini's study by sending letters to the FCT Editor or through online petitions.

Dr Angelika Hilbeck, senior scientist, Swiss Federal Institute of Technology, Institute of Integrative Biology IBZ, Zurich, Switzerland; Chair, European Network of Scientists for Social and Environmental Responsibility (ENSSER):

> "This retraction lacks any scientific basis. If the lack of 'definitive conclusions' were a valid reason for retraction, our libraries would be almost empty, as I have yet to see a study that yielded results of 'definitive' conclusiveness.In fact, the surprising revelation of FCT's highly irregular post-publication evaluation process is that Séralini's study would appear to be flawless. To me, this is a confirmation of the quality of the study and the integrity of the researchers, as very few studies would pass such an extraordinary evaluation process."

Dr Michael Antoniou, a molecular geneticist, London, UK:

> "Dr A. Wallace Hayes, only highlighted two of several aspects of the paper – the tumours and mortality rates – as 'inconclusive'. This suggests that even in the editor's view, the bulk of the findings – the severe organ toxicity in rats fed GM maize and low levels of Roundup – must be valid. To retract the whole paper based on the perceived inconclusiveness of just a proportion of the data presented is scientifically untenable."

Dr David Schubert, professor, Salk Institute for Biological Studies, CA, USA:

> "I am convinced that there is significant evidence, like that presented by Séralini, that some GM foods are hazardous to human health. In order for data supporting this possibility to enter public discourse, scientists must place their ethical responsibilities above corporate profits and cease their continual assault on the science relating to GM food's safety. The protection of scientists' right to publish their findings without censorship or retribution must be preserved."

More than 180 international scientists have signed the petition to support the Séralini team on the website **End Science Censorship** to complain about the retraction of the study.

Republish the study in open source in order to advance science

Séralini's study has been republished in open access and its raw data is now made public

Following the illegitimate removal of the long-term toxicology study on GM maize NK603 and its associated herbicide, Roundup, the research team of Professor Séralini was offered by several other scientific publishers support for republishing the study. **It is necessary to restore these unpublished scientific works so that science can reclaim its rights against the pressures of the industry seeking to suppress 'whistle-blowers'.**

To have a positive outcome to this debate, the research team of **Professor Séralini has chosen to republish its study with the Springer Publishing Group in a journal in open access (to be unveiled at the press conference) and having a professional peer-review committee**.

With the opportunity of republication by Springer Open, the Séralini team **will also provide the scientific community with the raw data of its study**, something that the industry has always refused to do under the premise of "trade secrets" or "intellectual property". The team believes that the industry has never achieved adequate testing, and has some data which indicates that there has never been blood analysis on rats contaminated by Roundup.

In January 2013, ANSES (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail - National Agency for Food, Environmental and Occupational Health Safety), in the person of its director **Marc Mortureux, confirmed to Prof. Séralini in writing that there is no toxicological analysis of Roundup** in its most complete formulation on animals over a two year period, adding that there are only a few studies on acute toxicity (from a few days to 3 weeks) without any blood testing.

The choice of engaging in the dynamics of *open science* has always been made by these researchers, as has the need for transparency in order to advance collaborative science based on knowledge sharing and research for the good of the public.

Open access also ensures high visibility; a previous article [2] of the Séralini team in *Environmental Sciences Europe* in March 2011 was viewed more than 120 000 times !

2 Gilles-Eric Séralini, Robin Mesnage, Emilie Clair, Steeve Gress, Joël de Vendômois, Dominique Cellier *Genetically modified crops safety assessments: present limits and possible improvements,* Environmental Sciences Europe 2011, 23 : 10-20

The message of the editor: “To support rational scientific debate rather than censorship”

The republication of the study will be accompanied not only by a new article by the Séralini team on the influence of conflicts of interest in the world of publishing and of health expertise (paper joined), but also by a message from the Editor explaining his approach:

> **“Empirical natural and social sciences produce knowledge (in German: Wissenschaften schaffen Wissen) which should describe and explain past and present phenomena and to estimate their future development. To this end quantitative methods are used. Progress in science needs controversial debates aiming at the best methods as basis for objective, reliable and valid results approximating what could be the truth. Such methodological competition is the energy needed for scientific progress. In this sense, ESEU aims to enable rational discussions dealing with the article from G.-E. Séralini et al. (Food Chem Toxicol 2012, 50:4221–4231) by re-publishing it. By doing so, any kind of appraisal of the paper´s content should not be connoted. The only aim is to enable scientific transparency and, based on this, a discussion which does not hide but focus methodological controversies.”**

The name of the publisher and of the Springer journal publishing the study will be released on the day of the press conference.

Press conference and contact

A press conference will be held in Paris on June 24, 2014 at 11:00 at Paris, Salle du bureau d'information du Parlement européen, 288 bvd St Germain (métro 12, Assemblée nationale) to reveal the name of the journal and answer your questions. A press release will be sent with additional informations at 11:00.

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