(Full) Reasoning of the Jury

for the 2015 Whistleblower Award to

Professor Gilles-Eric Séralini

This year, one of the recipients of the Whistleblower Prize awarded by the Federation of German Scientists (VDW) and the German Section of the International Association of Lawyers Against Nuclear Arms (IALANA) is **Professor Dr. Gilles-Eric Séralini**, a molecular biologist at the University of Caen (Normandy, France) whose particular research interests are focussed on the effects of the use of pesticides on health, including the 'weedkillers' glyphosate-based herbicides.

The Whistleblower Prize honours people who, for the sake of public benefit and in spite of possible negative consequences for themselves, disclose major grievances or negative developments which pose significant risks or danger to humans, society, the environment or peace. As insiders or experts who have highly relevant insights and knowledge coupled with the courageous willingness to benefit the public by raising the alarm, within the fields of R&D, state administration, the economy or international relationships whistleblowers often provide the only opportunity to uncover risks and dangers for important legally protected goods (*Rechtsgüter*) such as life and health.

Prof. Séralini fulfils these criteria in many ways.

I. Publicly Revealing Risks to Life and Health

1. Prof. Séralini and his group of researchers at the University of Caen and CRIIGEN[1] have been conducting scientific studies and publishing papers for many years to inform the public, the scientific community and the competent European and national authorities about their research results indicating serious risks resulting from, or at least possibly resulting from, the application of the world's most widely used herbicide – the glyphosate-based Roundup. This is particularly significant for important, legally protected goods (*Rechtsgüter*) such as life and health or the environment, since it has been demonstrated that this substance and its degradation products are widely present in our food and environment, including in humans and animals[2,3,4]. Since 1974, the corporation Monsanto has been selling a range of broad-spectrum herbicides, under the brand name Roundup, which are being used in agriculture and private gardens in over 130 countries, including Germany. The individual Roundup products differ in their salt formulations, the adjuvants, the medium (water solution or granulate), and

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

[2] Aris A, S Leblanc 2011. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. Reproductive Toxicology 31(4): 528 - 33.

[3] International Agency for Research on Cancer / World Health Organization. 2015. Glyphosate. IARC Monographs 112.

[4] Krüger M, P Schledorn, W Schrödl, H-W Hoppe, Wa Lutz, A A Shehata. 2014. Detection of glyphosate residues in animals and humans. Journal of Environmental and Analytical Toxicology

the glyphosate concentration. In order to ensure better adhesion to and penetration of the plant surface, a surfactant is used. Generally this is polyethoxylated tallow amine (POEA).

a) In the long-term feeding study carried out by Prof. Séralini and his research group and published in 2012, over a period of two years, rats (Sprague-Dawley strain) were fed with genetically modified (GM) maize (Roundup-tolerant NK603) with and without Roundup, and another group fed without the GMO was given drinking water to which glyphosate-based herbicide had been added (two Roundup-branded herbicides, Weather Max and Roundup GT Plus). A total of 200 rats were included in the experiment, divided into nine test groups of 20 individuals each and one control group of 20 individuals. The control group, consisting of 10 female and 10 male animals, received the standard diet A04, which includes 33% conventional maize and unadulterated drinking water. The test groups also comprised 10 female and 10 male animals. Three of these groups received the GM maize NK603 (one test group each with 11, 22 and 33% maize in the standard diet) and three received GM maize NK603 treated with Roundup (one test group each with 11, 22 and 33% maize in the standard diet). The other 3 test groups received conventional maize (33%, standard diet) and also drinking water which had been supplemented with different levels of Roundup GT Plus. The feeding experiments were designed to investigate the toxicity of the glyphosate-based herbicide Roundup and the genetically modified feed maize NK603. The study was not designed to study cancer risk[5,6]. In particular, it was designed to replicate the rat-feeding study by Monsanto, which was a 90-day test; in an earlier study the research group of Prof. Séralini had already found indications of toxic effects[7], but these had been dismissed as biologically irrelevant by Monsanto[8]. The study was the first toxicity study with glyphosate-based Roundup with rats for a test period of two years, corresponding to the total lifespan of the rats.

[5] "Future studies employing larger cohorts of animals providing appropriate statistical power are required to confirm or refute the clear trend in increased tumor incidence and mortality rates seen with some of the treatments tested in this study. As already stated, our study was not designed as a carcinogenicity study that would have required according to OECD the use of 50 rats per sex per group."
in: Séralini G-E, E Clair, R Mesnage, S Gress, N Defarge, M Malatesta, D Hennequin, J Spiroux de Vendômois. 2014. Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Environmental Sciences Europe 26: 14.

[6] This is also correctly referred to in the evaluation of *this* study by the IARC, see ibid p. 35 at 3.21, see Footnote 2

[7] Spiroux de Vendômois J, F Roullier, D Cellier, G-E Séralini. 2009. A comparison of the effects of three GM corn varieties on mammalian health. International Journal of Biological Sciences 5(7): 706 - 26.

[8] "The Monsanto authors adapted Guideline 408 of the Organization for Economic Co-operation and Development (OECD) for their experimental design. Our study design was based on that of the Monsanto investigation in order to make the two experiments comparable, but we extended the period of observation from Monsanto's 90 days to 2 years. We also used three doses of GMOs (instead of Monsanto's two) and Roundup to determine treatment dose response, including any possible non-linear as well as linear effects. This allowed us to follow in detail the potential health effects and their possible origins due to the direct or indirect consequences of the genetic modification itself in the NK603 GM maize, or due to the R herbicide formulation used on the GM maize (and not G alone), or both. Because of recent reviews on GM foods indicating no specific risk of cancer, but indicating signs of hepatorenal dysfunction within 3 months, we had no reason to adopt a carcinogenesis protocol using 50 rats per group. However, we prolonged to 2 years the biochemical and hematological measurements and measurements of disease status, as allowed, for example, in OECD protocols 453 (combined chronic toxicity and carcinogenicity) and 452 (chronic toxicity). Both OECD 452 and 453 specify 20 rats per sex per group but require only 50% (ten per sex per group, the same number that we used in total) to be analyzed for biochemical and hematological parameters. Thus, these protocols yield data from the same number of rats as our experiment. This remains the highest number of rats regularly measured in a standard GM diet study, as well as for a full formulated pesticide at very low environmentally relevant levels." in: Seralini et al. 2014, see Footnote 4

Various foundations, as well as public and private funders[9, 10] financed the study, which cost approximately 3.2 million Euros.

b) Prof. Séralini and his research group colleagues published the results of their feeding study with the title "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" on 19 September 2012 in the international scientific journal *Food and Chemical Toxicology* (FCT), published by Elsevier. The study was published after going through the usual quality assurance process (here: 5 reviewers) for scientific publications – the 'peer review' by independent external specialists. In their study, Prof. Séralini and his co-authors observed a strong increase in tumour formation in rats treated with Roundup and GM maize NK603, which occurred much earlier than in the control group rats. According to the research results, female rats died earlier and more frequently, developing tumours earlier than the animals that did not receive GM maize in their feed or Roundup in their drinking water. Tumours were also more frequent and earlier in male rats; liver damage was also diagnosed. Kidney damage was also observed for rats of both genders. Based on the results of their feeding study, Prof. Séralini and his scientific colleagues hypothesise that the foreign gene present in NK603 GM maize could interfere with the animals' metabolism, possibly with co-interference of the glyphosate-based herbicide Roundup. They presented this hypothesis in their publication and in public presentations, where they also showed shocking images of the laboratory rats with large tumours. Further significant conclusions from the study were that the current methods of risk assessment for genetically GM plants and herbicides are inadequate. Additionally, Prof. Séralini came to the conclusion that the current protocols for 90-day animal feeding studies are too short for a realistic determination of the possible health risks of Roundup and NK603 GM maize. He called for full and complete publication of the data that companies submit to regulatory agencies for their assessment of new active ingredients (here declared to be glyphosate) and authorisation of market-ready products (here: the Roundup herbicide range) so they can be examined by other independent scientists.

c) Immediately after publication severe accusations and personal attacks were launched against Professor Séralini[11]. A seemingly orchestrated campaign by 'interested parties', including those from the chemical industry[12] and the British Science Media Centre[13], which are mainly funded by the chemical industry and their lobby organisations[14], included

[9] "We gratefully acknowledge the Association CERES, for research on food quality, representing more than 50 companies and private donations, the Foundation 'Charles Leopold Mayer pour le Progrès de l'Homme', the French Ministry of Research, and CRIIGEN for their major support." in: Séralini et al. 2014, see Footnote 4.

[10] In particular, Fondation Charles Léopold Mayer pour le progrès de l'Homme made a significant contribution. FPH. 2012. Soutien de la fondation à l'étude du Criigen sur les effets à long terme des OGM. Press release from 19.09.2012 http://www.fph.ch/article135.html

[11] on this, see Vidal J. 2012. Study linking GM maize to cancer must be taken seriously by regulators. The Guardian, 28.09.2012. http://www.theguardian.com/environment/2012/sep/28/study-gm-maize-cancer

[12] Monsanto, 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Monsanto comments from 01.11.2012.
http://www.monsanto.com/products/documents/productsafety/seralini-sept-2012-monsanto-comments.pdf

[13] Science Media Centre. 2012. Expert reaction to GM maize and tumours in rats. Comments from 19.09.2012.
http://www.sciencemediacentre.org/expert-reaction-to-gm-maize-causing-tumours-in-rats
All publications of the SMC with the keyword "Séralini": http://www.sciencemediacentre.org/?s=seralini&cat=

[14] Science Media Centre: funding. http://www.sciencemediacentre.org/about-us/funding/

vehement ad-hominem attacks on the integrity of Professor Séralini[15]. Already on the day of publication, discrediting comments by eight scientists were posted who for years have been publicly and enthusiastically supporting applications of genetic engineering. None of them, however, has a documented track record as rat feeding study expert. Consequently, these comments were hardly meant as a sincere contribution to the scientific discussion of the study's contents. They peaked in accusations that Prof. Séralini had failed to meet ethical and scientific minimal standards: e.g. "The study appeared to sweep aside all known benchmarks of scientific good practice and, more importantly, to ignore the minimal standard of scientific and ethical conduct" or "Throughout their manuscript, Séralini et. al. ignore clear indications that there is something fundamentally wrong in their experimental design"[16]. These attacks on the personal and scientific integrity of Prof. Séralini continue until the present day. Insofar as the critics actually presented tangible, factual arguments, they include among others, that the number of test animals was too low and did not allow conclusions to be made about the carcinogenic effects of GM maize NK603, Roundup or glyphosate; the rat strain chosen is not suitable for studies of this type since it develops a high incidence of tumours anyway; earlier studies with GM maize and glyphosate did not exhibit any such noticeable results, so there must be something wrong with the results of this study. In Germany, the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Risk Assessment (BfR) also criticised the feeding study and the conclusions drawn from it by Prof. Séralini[17].

2. In Autumn 2013, the severe attacks on Prof. Séralini and his research team led the Editor-in-Chief of the journal *Food and Chemical Toxicology*, A. Wallace Hayes, to formally retract the 2012 publication on grounds of "inconclusiveness" (see Retraction Statement in the Appendix).

a) Prior to this decision, in February 2013 a previously non-existent post of Associate Editor for Biotechnology had been created at the journal. The journal's management appointed Professor Richard E. Goodman to this post and entrusted him with the Séralini article. Until 2004, Professor Goodman was an employee of the Monsanto corporation and was, or still is, a member of the International Life Sciences Institute (ILSI), which is a lobby organisation supported by the GM industry[18, 19] that had been stripped of certain priviliges associated with the status of a non-profit organisation by the WHO because of its proximity to the industry[20]. Many people presume that the retraction of the Séralini publication was the task assigned to

[15] The way the campaign against Professor Seralini progressed is documented here: Matthews J. 2012. Smelling a corporate rat: Séralini attackers exposed. Spinwatch from 12.12.2012.
http://www.spinwatch.org/index.php/issues/science/item/164-smelling-a-corporate-rat

[16] On the way these types of criticism are being dealt with, see: Loening U E. 2015. A challenge to scientific integrity: a critique of the critics of the GMO rat study conducted by Gilles-Eric Séralini et al. (2012). Environmental Sciences Europe (2015) 27: 13

[17] Statement from the German Federal Institute for Risk Assessment (BfR): 2012. Veröffentlichung von Seralini et al. zu einer Fütterungsstudie an Ratten mit gentechnisch verändertem Mais NK603 sowie einer glyphosathaltigen Formulierung. Stellungnahme Nr. 037/2012, 28 September 2012. http://tinyurl.com/p5v35pb

[18] Robinson C, J Latham. 2012. The Goodman affair: Monsanto targets the heart of science. Independent Science News, 20.05.2013.
https://www.independentsciencenews.org/science-media/the-goodman-affair-monsanto-targets-the-heart-of-science/

[19] on this, see the evidence in: Mertens M. (undated). Der Fall Séralini. Schule und Gentechnik.
http://www.schule-und-gentechnik.de/lehrer/fallbeispiele/der-fall-seralini

[20] Lougheed T. 2006. Policy: WHO/ILSI affiliation sustained. Environmental Health Perspectives 114(9): A521:

Prof. Goodman[17, 18] which appears to be confirmed indirectly with this newly created post at the journal disappearing as quickly again after the retraction of the Séralini paper as it had been created. And with it any connection to Prof. Goodman. Procedures such as these are extremely unusual at serious academic journals.

b) The official retraction of the paper by *Food and Chemical Toxicology* meant that with immediate effect Prof. Séralini's study and its data could no longer be cited. In other words, they had been 'removed from public debate'. Furthermore, regulatory authorities no longer needed to consider them in their assessments.

c) The Committee on Publication Ethics (COPE – established by peer review journals) ruled that this procedure was a clear breach of international ethical guidelines[21] since withdrawing papers and the data they contain is only justified in cases of severe offences such as demonstrable falsification or manipulation, "honest error" or plagiarism and not in cases of "inconclusiveness" determined after publication.

In this way, the whole affair surrounding this feeding study obviously presents us with a 'textbook lesson' on how an academic journal of a large publisher succumbs under the strong pressure from 'interested parties' and officially retracts a paper 'merely' because the study makes public scientific findings that are unfavourable to certain – economically powerful – parties.

3. A detailed analysis of the campaign against the publication of the paper can be found in the review "The Seralini affair: Degeneration of Science to Re-Science?"[22]. Two core points in the criticism of Séralini's methodology (ten per gender is a low number of experimental animals, and the Sprague-Dawley rat strain is genetically susceptible to tumour formation) were carried into the sphere of public debate with great vehemence by numerous scientists, bloggers and other disseminators – with the result that some journalists[23] and certain parties in the public discourse have adopted the accusations without critical questioning. The review from Meyer and Hilbeck mentioned above takes a closer look at these accusations and comes to two significant conclusions:

- The rat strain Sprague-Dawley used by Séralini in his 2012 feeding study is the standard strain selected for use in the world's two largest research projects investigating toxicity and carcinogenicity – the National Toxicology Program at the US Department of Health and Human Services and the Ramazzini Foundation Cancer Program at the European Ramazzini Foundation for Oncology and Environmental Sciences. Within the last 20 years, it was also used in at least 21 long-term studies on toxicology and carcinogenicity whose results were published in recognised scientific journals.

[21] Committee on Publication Ethics. 2009. Retraction Guidelines.
http://publicationethics.org/files/retraction%20guidelines_0.pdf

[22] Fagan J, T Traavik, T Bøhn. 2015. The Seralini affair: Degeneration of Science to Re-Science? Environmental Sciences Europe 27: 19.

[23] Herrmann S. 2015. Aktivist statt Whistleblower. Süddeutsche Zeitung, 19.09.2015.
http://www.sueddeutsche.de/wissen/gentech-kritiker-aktivist-statt-whistleblower-1.2653306
Bahnsen U. 2015. Ausgezeichnete Pfeife. Die Zeit, 24.09.2015. (not published in the online edition)

- In the OECD guideline, applicable to the Seralini study, on 2-year feeding experiments with rats to investigate the toxicity (not carcinogenicity) of specific substances recommends the use of groups of 20 animals, but for the investigation of toxicity only 10 of those 20 rats have to be used for analyses. In its studies, Monsanto followed this guideline by taking 20 rats per group but applying unknown criteria to select only 10 of them for the biochemical analyses. Prof. Séralini limited the group to 10 from the beginning of the study and then subjected *all* of the animals in the group to the biochemical analyses. EFSA and all other critics mention the number '20 per group' without further clarifying that actually only 10 out of these 20 need to be examined.

4. Professor Séralini did not let himself be discouraged by the 'retraction' of his paper on the toxicity of Roundup (together with NK603 GM maize) and its associated consequences for health and life (increased susceptibility to tumours etc.). Instead, he actively worked to have it republished or published elsewhere. Eventually, he managed to have his paper re-published, with almost no changes, in 2014 in the journal *Environmental Sciences Europe* published by Springer: "Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize"[24]. In the newly published paper, it is (once again) expressly indicated that the observations of tumour formations were not actually the primary focus of this study and that they are not conclusive on their own and that a full carcinogenicity study should now be the logical consequence of the data and insights gained:

"*..., this initial investigation was designed as a full chronic toxicity and not a carcinogenicity study. Thus, we monitored in details chronologically all behavioral and anatomical abnormalities including tumors. A full carcinogenicity study, which usually focuses only on observing incidence and type of cancers (not always all tumors), would be a rational follow-up investigation to a chronic toxicity study in which there is a serious suspicion of carcinogenicity."*

5. In further publications, Professor Séralini and his team of researchers[25, 26] have also drawn attention to the potential risks of the adjuvants used in the glyphosate-based herbicide Roundup – specifically the surfactants which are intended to increase the efficacy of glyphosate, such as the polyethoxylated tallow amine (POE-15)[27]. The additive POE-15 lead to a higher toxicity for glyphosate than previously generally accepted, since inner organs in the test animals such as the kidney and liver showed signs of toxicity. In humans, the Roundup adjuvant POE-15 could probably affect the hormone balance and there is also some indication that in combination with glyphosate it is probably carcinogenic.

6. Prof. Séralini also came to further conclusions. He highlighted the systemic weaknesses in the testing of herbicides and in particular in the run-up to the market launch of the glyphosate-

[24] Seralini et al. 2014, Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize - page 3 - http://www.enveurope.com/content/26/1/14

[25] Benachour N, G-E Seralini. 2009. Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic, and placental cells. Chemical Research in Toxicology 22(1): 97 - 105.

[26] Mesnage R, B Bernay, G-E Séralini. 2013. Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity. Toxicology 313(2-3): 122 - 8.

[27] This substance is no longer permitted as an adjuvant in Germany.

based herbicide Roundup, especially in connection with GM plants that are evaluated in isolation from the pesticides that are inserted into or applied onto them in practice[24, 28, 29].

The initial and renewed authorisation of the herbicidal active ingredient glyphosate is jointly decided by the EU Commission and all EU member states on the basis of a recommendation from the European Food Safety Authority (EFSA)[30]. A subsequent procedure then decides whether the plant protection product (e.g. Roundup) – i.e. the specific market-ready formulation of medium, active ingredient and adjuvants – can be approved for an EU zone for the specific requested application. Since there is still no EU Implemention Regulation for this subsequent step, it currently is enacted according to national law, which in Germany means §§42, 43 of the Plant Protection Act.

The approval and accreditation procedures for herbicides, especially in connection with GM plants, where their most intensive application occurs, has long been the subject of criticism[31, 32].

In particular, the lack of transparency is the focus of the criticism. One of the issues is the *de facto* massive weight placed on the studies and data submitted by the applicant companies compared to the minor role assigned to studies conducted by independent scientists. Furthermore, most of the studies underlying the applications are never published and, thus, have not been subjected to independent peer review.

Based on the statements and reasonings published by industry-oriented scientific parties and regulatory authorities in recent years, it has become clear that critical analyses of the methodology employed in research on health effects of pesticides (with or without GM) are only triggered when the published data casts doubt on the safety of GM plants or their corresponding pesticides – i.e. when the published results could negatively influence the general public's acceptance of genetic engineering and pesticides.

The first example that triggered a wave of worldwide reporting concerned the biochemist Arpad Pusztai, who was the recipient of the VDW and IALANA Whistleblower Award in 2005[33]. This is not the place to report again on the impact of his publication "Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small

[28] Séralini G-E, J Spiroux de Vendômois, D Cellier, C Sultan, M Buiatti, L Gallagher, M Antoniou, K R Dronamraju. 2009. How subchronic and chronic health effects can be neglected for GMOs, pesticides or chemicals. International Journal for Biological Sciences 5(5): 438 - 43.

[29] Séralini G-E, R Mesnage, E Clair, S Gress, J Spiroux de Vendômois, D Cellier. 2011. Genetically modified crops safety assessments: present limits and possible improvements. Environmental Sciences Europe 23: 10.

[30] The basis for the authorisation is the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. This came into power on 14 December 2009. It replaced 91/414/EEC (pesticide guideline) and 79/117/EEC.

[31] Hilbeck A, H Meyer, 2012. Die Risikoabschätzung gentechnisch veränderter Pflanzen ist unzureichend. Die Zeit, 07.03.2012. http://www.zeit.de/wissen/umwelt/2012-02/gruene-gentechnik-debatte-gastbeitrag
Hilbeck A, M Meier, J Römbke, S Jänsch, H Teichmann, B Tappeser. 2012. Environmental risk assessment of genetically modified plants - concepts and controversies. Environmental Sciences Europe 23: 13.

[32] Cuhra M. 2015. Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environmental Sciences Europe 27: 20.

[33] see Deiseroth/Falter (ed.), Whistleblower in Gentechnik und Rüstungsforschung [*Whistleblowers in the Genetic Modification and Arms Sectors*]. Berlin, 2006.

intestine"[34] from 1999, but rather on the lack of any reaction to another paper of him which appeared in the same year: "Expression of the insecticidal bean alpha-amylase inhibitor transgene has minimal detrimental effect on the nutritional value of peas fed to rats at 30% of the diet."[35] In the experiments of this study, transgenic peas were fed to rats and no negative effects were observed. This obviously did not trigger any criticism of the methodology, although at least one point of criticism was applicable to both studies: the number of test animals was lower than the number recommended by the OECD guidelines for feeding experiments (although there are no OECD standards for feeding tests with GMOs). This means that the lack of negative effects could theoretically be a result of statistical effects: it could represent a 'false negative'. However, this did not result in a pedantic analysis of the methods employed from either the competent authorities or the 'interested parties'. However, as far as public health is concerned, 'false negatives' (the non-discovery of a harmful effect that actually is present) are much more problematic than 'false positives' (the apparent discovery of a harmful effect that is subsequently shown not to be present).

A more recent well-known example of this practice of result-triggered criticism of methodologies is a review article that is often cited in connection with the Séralini feeding study "*Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review*"[36]. Like the Séralini study, this review was also published in 2012 in the journal *Food and Chemical Toxicology*. For Séralini's critics, this review is regarded as the 'crown witness' or authoritative source, since it concludes that in numerous other long-term studies there was no evidence of negative effects from GM feed plants on laboratory animals[37]. However, in their analysis of 24 feeding studies the authors of this review list in fact numerous methodological weaknesses and even obvious errors. For example, only ten of the studies actually used the isogenic parent plants of the transgenic feed plants as the proper control feedstuff, which means the results of the other 14 studies have only low validity since they do not make a scientifically sound comparison. Remarkably, Snell et al. only highlight these methodological weaknesses and errors in order to disqualify studies whose results were negative for the supporters of GM plant diets but not for the studies that found no effects on health. Where a study delivered no argument against the application of genetic engineering, serious errors in its methodology were ignored and accepted nonchalantly, even if there should be a pressing suspicion that these errors could have led to it missing harmful effects, resulting in a 'false negative'. Based on this approach, which is obviously unscientific, the review concludes that the long-term studies prove that GM plants are nutritionally equivalent to their non-GM counterparts and that they can be used safely in food- and feedstuffs. This biased review, founded on an unscientific double standard,

[34] Ewen SWB, A Pusztai. 1999. Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. Lancet 356 (9178): 1553 - 4.

[35] Pusztai A, G Grant, S Bardocz, R Alonso, M J Chrispeels, H E Schroeder, M L Tabe, T J V Higgins. 1999. Expression of the insecticidal bean α-amylase inhibitor transgene has minimal detrimental effect on the nutritional value of peas fed to rats at 30% of the diet. The Journal of Nutrition 129(8): 1597 - 1603.

[36] Snell C, A Bernheim, J-B Bergé, M Kuntz, G Pascal , A Paris, A E Ricroch. 2012. Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. Food and Chemical Toxicology 50(3-4): 1134 - 38.

[37] see the papers referred to in the discrediting letter to FCT: Letter to the editor, 07.12.2012. http://www.sciencedirect.com/science/article/pii/S0278691512007922

was not retracted by the journal but instead held up as evidence to ‘counter’ Séralini’s research results.

In the case of the feeding study by the Séralini group, this style of result-triggered and interest-oriented criticism of methodologies reached new heights. A comparative evaluation of the answers from the European Food Safety Authority to the research results submitted by Monsanto for its successful application for approval of NK603 maize with the EFSA response to the publication by Séralini reveals that also EFSA applied a double standard when it came to assessing underlying methodologies. The review by Meyer & Hilbeck (2013) “*Rat feeding studies with genetically modified maize - a comparative evaluation of applied methods and risk assessment standards*”[38], documents how both studies actually suffered from similar deficits in four of the five criteria used by EFSA. However, EFSA did and does not apply these criteria to evaluate the studies by Monsanto, which showed no risk in using NK603 maize as feedstuff. Both studies (from Monsanto and Séralini) were carried out and published before the publication of these assessment criteria but EFSA only applied them to the study by Séralini.

7. In spite of the sustained attacks on his personal and scientific integrity by representatives of ‘interested parties’, Prof. Séralini did not back down in the conflicts triggered by his papers. He defended himself against defamation, even taking some accusers to court, such as in his successful 2011 case against Marc Fellous from the French Association for Plant Biotechnology (AFBV)[39].

Regarding the objections raised against the results of his feeding study, with great stamina and decisiveness he maintained his professional ethics and countered the arguments at a high scientific level, furthering the necessary public and scientific discourse in a variety of ways. In doing so, in many countries he inspired and enabled a public debate on the risks associated with glyphosate and the herbicide products based on it, which are sold in many markets under many different brand and product names.

a) His counterarguments, which he also presented publicly and with vehemence, were published in academic journals, including at least four in *Food and Chemical Toxicology*[40]. There are no documented lapses: Professor Séralini did not resort to discrediting, ad hominem strategies like those favoured by many of his opponents.

This attitude and the results of his work gained him the worldwide support of many scientists who defended the methods he chose and deemed his research results to represent genuine

[38] Meyer H, A Hilbeck. 2013. Rat feeding studies with genetically modified maize - a comparative evaluation of applied methods and risk assessment standards. Environmental Sciences Europe 25: 33.

[39] Agence France Press. 2011. OGM/diffamation: chercheur condamné. Le Figaro, 18.01.2011. http://www.lefigaro.fr/flash-actu/2011/01/18/97001-20110118FILWWW00568-ogmdiffamation-chercheur-condamne.php

[40] Mesnage et al. 2014. Letter to the Editor regarding 'Delaney et al., 2014': Uncontrolled GMOs and their associated pesticides make the conclusions unreliable. Food and Chemical Toxicology 72: 322.

Seralini et al. 2014. Conclusiveness of toxicity data and double standards. Food and Chemical Toxicology 69: 357 - 9.

Seralini et al. 2014. Retraction notice to 'Long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize' [Food and Chemical Toxicology, Volume 50: 4221-4231]. Food and Chemical Toxicology 63: 244.

Seralini et al. 2013. Answers to critics: Why there is a long term toxicity due to a Roundup-tolerant genetically modified maize and to a Roundup herbicide. Food and Chemical Toxicology 53: 476 - 483.

scientific progress[41]. However, they do not claim his results allow for final conclusions, in contrast to what some critics accuse them to do.

One of the counter-arguments posited by Seralini's critics regarding the supposedly unsuitablility of the strain of laboratory rats chosen for the feeding study because of their increased cancer susceptibility with the increasing age of the rats does not challenge the validity of the core results of the feeding study by Séralini. The Seralini study clearly shows an important result: the 'tumour-free' period before the development of any cancer was distinctly shorter in the test groups of rats fed with various proportions of GM maize NK603 or Roundup[42]. This is evidence for the validity of Séralini's conclusions and demonstrates a need for further research. It certainly does not justify the attacks on Prof. Séralini's personal or scientific integrity.

b) Further support for the association of glyphosate as an active ingredient in herbicides with the existence of risks to important legally protected goods (*Rechtsgüter*) such as life and health can be found in the categorisation of glyphosate as "probably carcinogenic to humans (Group 2A)" by the International Agency for Research on Cancer (IARC) on 20 March 2015 – a working group of the World Health Organization (WHO) in Geneva[43]. Within three days of initial publication of the IARC report, the website "Academics Review - Testing popular claims against peer-reviewed science"[44] (founded by two biotechnology professors) organised a campaign also against this report, in spite of the fact it was based on 200 peer-reviewed articles. The scientific studies reviewed by the IARC on the effects of the herbicide Roundup and its active ingredient glyphosate included seven papers published in the last ten years by the Séralini group. While some in the public discourse, in particular in the runup to this year's Whistleblower Award, postulate that the IARC report considered the 2012 study from Séralini to be inadequate for judging the carcinogenic potential of glyphosate (because of the low animal number)[45], these comments neglect to mention the fact that the IARC working group at the WHO had no such reservations about including other studies conducted by Séralini and his group. In fact, it was Professor Séralini himself who first pointed out that his research cannot lead to a final conclusion on cancer and further research is needed[23] so the claim of some critics that the IARC report led to an 'invalidation' of the Séralini study is not based on factual evidence in the IARC report.

On 14 August, Professor Séralini's group 'raised the stakes' again with a new publication in the very same journal that had retracted the 2012 paper, *Food and Chemical Toxicology*. The

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[41] End Science Censorship. 2014. 150 scientists condemn retraction of Séralini study as bow to commercial interests. Press release, 04.03.2014. http://www.endsciencecensorship.org/en/page/press-release#.VhFbr6S3Ix2
http://www.endsciencecensorship.org/en/page/Statement#signed-by
Independent Science News. 2012. Seralini and Science: an Open Letter, 02.10.2012.
http://www.independentsciencenews.org/health/seralini-and-science-nk603-rat-study-roundup

[42] on this, see, i.a., Loening U E. 2015. A challenge to scientific integrity: a critique of the critics of the GMO rat study conducted by Gilles-Eric Séralini et al. (2012). Environmental Sciences Europe (2015) 27: 13

[43] IARC/WHO 2015, see Footnote 2.

[44] Anonymous, 2015. IARC glyphosate cancer review fails on multiple fronts. Academics Review, 23.03.2015.
http://academicsreview.org/2015/03/iarc-glyphosate-cancer-review-fails-on-multiple-fronts/

[45] for example: Weß L. 2015. Erinnerungen an die Wirklichkeit: Séralini und die Fakten. Blog entry, 20.09.2015.
http://ludgerwess.com/erinnerungen-an-die-wirklichkeit-seralini-und-die-fakten/

paper is entitled “Potential toxic effects of glyphosate and its commercial formulations below regulatory limits”[46]. This review article was written by Professor Séralini and three more scientists involved in the study behind the paper retracted in 2013 by the Editor-in-Chief. In it they survey existing scientific publications and conclude that even at permitted environmental concentrations of glyphosate, teratogenesis (malformation of embryos), increases in tumour formation and kidney failure can occur.

8. Recently, in September 2015, the international and national debate on glyphosate escalated further.

a) In a statement on glyphosate, the WHO called for one of its working groups to improve the discussion surrounding glyphosate[47]. Specifically, the “Main findings and recommendations of the WHO Core Assessment Group on Pesticides, Expert task force on Diazinon, Glyphosate and Malathion” concludes with:

i) The task force recommends full re-evaluation of glyphosate, malathion and diazinon by Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

ii) The task force recommends that JMPR reviews internal guidelines to consolidate the criteria for data inclusion/exclusion with respect to published and/or proprietary data sources.

Translated from diplomatic into plain language, it means: “Back to square 1!” and “Please distinguish between scientific publications and those submitted by ‘interested parties’.”

This also puts more pressure on the German Federal Institute for Risk Assessment, member of the JMPR, and its re-evaluation of the active ingredient glyphosate for the EU Commission (see also the next section below).

b) In the run-up to a hearing on glyphosate in the German parliament, the German non-governmental organisations Campact and Pesticide Action Network (PAN) published a study by the toxicologist Peter Clausing[48]. Clausing reviewed a copy of the above-mentioned BfR report on the re-authorisation of glyphosate that was leaked to him. The BfR report has not yet been released to the public although it currently forms the main basis for any decision on extending the approval for glyphosate by the EU for another ten years. Clausing arrived at following conclusions: “The BfR report twists facts and either ignores or incorrectly presents the results of important studies on the cancer risks of glyphosate. It is therefore reasonable to conclude that the Federal Institute for Risk Assessment has deliberately played down the state of evidence against glyphosate.” For example, in the section on genotoxicity there is no consideration given to 44 scientific publications which demonstrated genotoxic effects but the

[46] Mesnage R, N Defarge, J. Spiroux de Vendômois, G-E Séralini. 2015. Potential toxic effects of glyphosate and its commercial formulations below regulatory limits. Food and Chemical Toxicology 84: 133 - 53.

[47] Joint FAO/WHO Meeting on Pesticide Residues. 2015. Main findings and recommendations of the WHO Core Assessment Group on Pesticides Expert task force on Diazinon, Glyphosate and Malathion. http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

[48] PAN Germany. 2015. Glyphosat-Bewertung: Warum das Bundesinstitut für Risikobewertung zu einem völlig anderen Urteil kommt als die Krebsforscher der WHO. Press information, 28.09.2015 and link to study, http://www.pan-germany.org/deu/~news-1354.html

report does include unpublished manufacturers' studies which report no carcinogenic effect. These conclusions are similar to those of an earlier review in 2011 by Antoniou and colleagues .on the role of the Federal Institute for Risk Assessment in the evaluation proces of glyphosate-based herbicides, who already complained of non-transparency and double standards[49]. This has to be taken into account when it comes to the assessment of the Séralini group study made by the BfR[50].

c) Since the glyphosate hearing in the German parliament, the SPD parliamentary group has taken a position in favour of withdrawing glyphosate from the market for private use as a precautionary measure and the phasing out of of glyphosate in agriculture until it is completely abandoned[51].

d) The governing parliamentary groups in the German federal state of Schleswig-Holstein (SPD, Bündnis 90/Die Grünen and SSW) submitted a proposal to the state parliament (*Landtag*) calling for a "Moratorium on the approval of glyphosate"[52]. In the motion, the state government is called on to decide, among other things, that a temporary suspension of the approval has to continue "until a decision has been taken at EU level on the renewal of approval, based on consideration of the WHO-IARC monograph and further current studies".

II. Whistleblowing which Primarily Serves the Public Interest

As a scientist, Professor Séralini's reacted in an examplary way since he did more than just draw attention to a global hazard for human health (from a herbicide used worldwide in large quantities): he also resisted massive attacks from fellow scientists by responding in publishing peer-reviewed articles which countered those attacks and supported or further developed the results from his studies that had triggered those attacks. He received support from many scientists who criticised the attacks on his personal integrity and positively responded to his scientific work[53]. Some of Seralini's critics accused him of seeking to gain material advantages for himself or those close to him by publishing his studies, but no tangible indications for this can be found. The scientific contributions from Prof. Séralini and his team furthered scientific discourse.

His steadfastness in the face of attacks on his personal and scientific integrity bear witness to a high awareness of his professional ethical responsibility. It is owed to his long-term,

[49] Antoniou M, M E El-Din Mostafa Habib, C V Howard, R C. Jennings, C Leifert, R O Nodari, C Robinson, J Fagan. 2011. Roundup and birth defects: Is the public being kept in the dark? Earth Open Source, UK. http://earthopensource.org/wp-content/uploads/RoundupandBirthDefectsv5.pdf

[50] Statement from the German Federal Institute for Risk Assessment (BfR), 2012, see Footnote 16.

[51] SPD parliamentary group, 2015. Glyphosat: Ausstieg aus der Nutzung vorantreiben. Press release, 28.09.2015, http://www.spdfraktion.de/presse/pressemitteilungen/glyphosat-ausstieg-aus-der-nutzung-vorantreiben

[52] Parliamentary group Die Grünen/Bündnis 90 Schleswig-Holstein. 2015. Moratorium für die Zulassung von Glyphosat . Press release, 01.10.2015 and link to application. http://sh-gruene-fraktion.de/thema/umwelt-agrar/moratorium-f%C3%BCr-die-zulassung-von-glyphosat

[53] On this see, i.a., Meyer & Hilbeck 2013, see Footnote 37; Loening U E. 2015. A challenge to scientific integrity: a critique of the critics of the GMO rat study conducted by Gilles-Eric Séralini et al. (2012). Environmental Sciences Europe (2015) 27: 13.

unswerving professionalism, backed up with an impressive number (c. 50) of peer-reviewed publications on the issue of glyphosate/Roundup alone (out of a total of over 100), that even EU regulatory authorities have seen the need to react. At least now the rat feeding studies will be repeated, at least partially. A further consequence is the expected significant limitation of the uses of glyphosate-based herbicides – perhaps even leading to a complete ban. Also in the future, rat feeding studies will be obligatory in connection with the approval of GM crops.

All of this can be traced back (mainly and in some cases solely) to the courageous engagement of Prof. Séralini and his tireless research activity. It is difficult to imagine that without the results and publications of Prof. Séralini and his team, research projects such as GRACE[54] or G-TWYST[55] or GMO90Plus[56] would have ever seen the light of the day. The scientific debate on the validity of the chosen methods in these listed projects and the continued influence of industry-oriented participants in these projects (especially GRACE) is in full swing again and must be allowed to continue[57].

III. Whistleblower Risking Retaliation

The (unjustified) retraction of the study published in 2012 by the journal *Food and Chemical Toxicology* almost ruined the scientific integrity of Prof. Séralini. In the period following, Prof. Séralini also had to justify his actions to his university because of the serious attacks he was facing. This barrage of attacks left its mark on the university management, where doubts began to arise, and put him under pressure to act because the university did not want to remain in a frequently very negative media spotlight. Prof. Séralini told one of the award jury members that all of this affected him very deeply. These conflicts resulted in a significant deterioration of his health. Protracted periods of illness took their toll over a period of years and in at least one case almost cost him his life – during a lecture tour in the UK. Only quick emergency medical assistance, expert diagnosis and treatment as well as highly professional care in the intensive care unit of a London hospital could save his life. It also took a toll in his personal life which will not be detailed here.

[54] GRACE (GMO Risk Assessment and Communication of Evidence). Grace in brief. http://www.grace-fp7.eu/en/content/grace-brief

[55] G-TwYST (Genetically modified plants Two Year Safety Testing). About G-TwYST. http://www.g-twyst.eu/

[56] GMO90plus. Recherche de biomarqueurs prédictifs d'effets biologiques dans l'étude de la toxicité sub-chronique (3 et 6 mois) des OGM chez le rat . http://www.rechercheriskogm.fr/page/GMO90plus

[57] Bauer-Panskus A, C Then. 2013. (DIS)-GRACE. Risk assessment on the leash of the biotech industry. Testbiotech background, 22.04.2013. https://www.testbiotech.org/sites/default/files/TBT%20Background%20GRACE_final_0.pdf

IV. Summary Tribute

With the results of his feeding study published in 2012, as well as his other studies and publications, Prof. Séralini has made significant contributions to the disclosure of risks to important legally protected goods (*Rechtsgüter*) such as life and health associated with, or at least possibly associated with, the glyphosate-based herbicide Roundup, especially in combination with genetically modified NK603 maize. In doing so he turned not only to his scientific colleagues but also to the general public, in order to draw attention to the risks he saw in an open and easily understandable way.

As the Whistleblower Award Jury, by investigating and stating this, and in particular by resisting the severe attacks on the personal and scientific integrity of Prof. Séralini, we are defending the freedom of scientific discourse and the professional ethical responsibility of scientists. However, we do not wish to position ourselves on one side or the other of the substantive scientific controversy between Prof. Séralini and his critics. We have neither the intent nor the competence to decide which side is 'right' regarding the evidence of increased frequency of tumours as well as liver and kidney damage in the test rats observed by Prof. Séralini in the feeding study. Nonetheless, we have to and can expect German and European agencies to follow up in every relevant way the evidence observed and the questions raised by Prof. Séralini and his research team regarding the risks and hazards to life and health associated with the use of the glyphosate-based herbicide Roundup. Their decisions cannot be made primarily or exclusively on the basis of expertise from 'interested parties'.

Frankfurt am Main/Berlin, in September 2015

The Whistleblower Award Jury:

Gerhard Baisch, lawyer (Bremen) Dr. Dieter Deiseroth, Federal Judge (Leipzig/Düsseldorf), Prof. Dr. Hartmut Grassl (Hamburg) - Dr. Angelika Hilbeck, agroecologist (Swiss Federal Institute of Technology, Zurich) - Christine Vollmer, lawyer (Bremen)

Appendix 1:

Retraction Statement regarding the Séralini study in Food and Chemical Toxicology*:* Unequivocally, the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data. However, there is legitimate cause for concern regarding both the number of animals in each study group and the particular strain selected. The low number of animals had been identified as a cause for concern during the initial review process, but the peer review decision ultimately weighed that the work still had merit despite this limitation. A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to overall mortality or tumor incidence. Given the known high incidence of tumors in the Sprague-Dawley rat, normal variability cannot be excluded as the cause of the higher mortality and incidence observed in the treated groups.

Ultimately, the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for *Food and Chemical Toxicology* ... The retraction is only on the inconclusiveness of this one paper.