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Press Release 17.12.2013

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End double standards in evaluating GMO safety studies – say scientists

Europe's food safety agency only criticises studies that find risk, new analysis shows

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The controversy about the Séralini et al. study, which reported negative health effects of Monsanto's NK603 GM maize and Roundup herbicide fed to rats over the long term,¹ is still going on. According to a new review published in *Environmental Sciences Europe*, the European Food Safety Authority (EFSA) used unscientific double standards to dismiss the Séralini study on genetically modified (GM) maize.²

The publication of this latest review comes just days after the retraction of the Séralini paper by Elsevier, the publisher of *Food and Chemical Toxicology* (FCT), on the unprecedented grounds of the “inconclusive” nature of some of the findings. ENSSER condemned the retraction³.

The Séralini study triggered an immediate storm of criticism by scientists and organisations, most of whom are known for their support of GMOs and their pleas for sweeping deregulation of GM plants in the EU and relaxation or even abandonment of risk assessment standards.⁴

Retrospective and selective application of new standards by EFSA

In September 2012, the European Commission asked EFSA to review the Séralini study. EFSA did so by retrospectively applying new standards released in 2011 to scientific work that Séralini planned and started in 2008.⁵ EFSA concluded that the Séralini study was “inadequate”.⁶

But EFSA did not apply these same standards retrospectively to the original rat feeding study by Monsanto, even though the underlying design for the Monsanto study was later repeated by Séralini.⁷ The

¹ Séralini G-E, E Clair, R Mesnage, S Gress, N Defarge, M Malatesta, D Hennequin, JS de Vendômois. 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food Chem Toxicol* 50: 4221-4231

² 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; <http://www.enveurope.com/content/25/1/33/about>

³ <http://www.ensser.org/democratising-science-decision-making/ensser-comments-on-the-retraction-of-the-seralini-et-al-2012-study/>

⁴ Science Media Centre: Study on cancer and GM maize - experts respond. Science Alert of 20.09.2012. <http://www.sciencemediacentre.co.nz/2012/09/20/study-on-cancer-and-gm-maize-experts-respond/>
Public Research and Regulation Initiative: Letter and Q&A - Séralini et al 2012; <http://www.prri.net/questions-and-answers/qa-seralini-et-al-2012/>

⁵ EFSA Scientific Committee. 2011. EFSA guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. *EFSA J* 9(12):2438

⁶ European Food Safety Authority. 2012. Review of the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in *Food and Chemical Toxicology*. *EFSA J* 10(10):2910

⁷ Hammond B R Dudek, J Lemen, M Nemeth. 2004. Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn. *Food Chem Toxicol* 42: 1003-1014

Monsanto study concluded that this same GM maize was safe to eat, resulting in the approval for consumption of this GM crop by millions of animals and EU citizens in 2005.

EFSA review undermined the basic principles of science

Hartmut Meyer, one of the authors of the new review, said, “Use of such double standards is a common response from scientists calling for GMO deregulation and, somewhat surprisingly, also from some government authorities, to studies that show negative environmental and health effects of GMOs. Only those studies that find problems are subjected to excessive scrutiny and rejected as defective. This approach appears to be a tactic to avoid dealing with ‘inconvenient’ results, whilst selecting for ‘convenient’ results.”

The new review then applied the same criteria used by EFSA to reject the Seralini study to 21 other 1-2-year feeding studies published in peer-reviewed scientific journals during the last 20 years. Those studies did not test feed derived from GM plants but mostly chemicals, used the same strain of rat, similar low numbers of tested animals and likewise modified protocols that extended or diverged to some degree from the strict OECD protocols and EFSA criteria as both Seralini and Monsanto did.

Restore scientific principles of objectivity

Angelika Hilbeck, the second author of the new review and chair of the European Network of Scientists for Social and Environmental Responsibility (ENSSER), said, “ENSSER wants to see scientific objectivity restored. We are calling for an end to the use of double standards, particularly by EFSA, in the evaluation of scientific research on substances that may pose risks to public health. We need a reasoned, respectful debate with the aim of reaching a consensus on the evaluation standards that must be consistently applied to all toxicity and carcinogenicity trials, regardless of whether they have findings that are ‘inconvenient’ for certain parties. EFSA should take the lead here.”

“It’s time to stop selectively attacking methods and begin to deal with the results.”

Double standards used to claim GMO safety

Another example of selective scrutiny of study methods in order to avoid dealing with the results is a review of GMO safety studies conducted by Snell et al. (2012)⁸. In their review of 24 animal feeding trials with GM plant-derived feed, the authors noticed severe methodological shortcomings in a majority of the analysed publications, e.g. isogenic lines as controls were only used in 10 studies. However, Snell et al. used these shortcomings as arguments to dismiss those studies stating negative effects – but not those stating safety. Based on this asymmetrical, result-triggered approach, the review incorrectly concludes that no health hazards were found in 24 analysed publications.

Notes for editors

Hartmut Meyer and Angelika Hilbeck are founding members of the European Network of Scientists for Social and Environmental Responsibility (ENSSER). The European Network of Scientists for Social and Environmental Responsibility (ENSSER) was founded in 2009 to improve the quality of basic and regulatory science used in the risk analysis of existing and emerging technologies and their products such as genetically modified organisms, chemicals, food technologies, geo-engineering, nanomaterials, and synthetic biology, including the risk of their military use. To enable such scientific work, ENSSER advocates the creation of spaces for scientific work independent from the influence of the developers and owners of current technologies, supports early-warning scientists and promotes their protection from discrimination and discreditation. ENSSER members are contributing to the current scientific debates on technology and risk assessment in modern biotechnology⁹, nanotechnology and other fields.

⁸ **Snell C, A Bernheim, J-B Bergé, M Kuntz, G Pascal, P Paris, AE Ricroch.** 2012. Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. *Food Chem Tox* 50:1134-1148

⁹ see for example "Implications for GMO-cultivation and monitoring", a thematic series in Environmental Sciences Europe; http://www.enveurope.com/series/GMO_cultivation