

Questionable Biosafety of GMOs, Double Standards and, Once Again, a "Shooting-the-Messenger" Style Debate¹

Summary and Main Issues

The European Network of Scientists for Social and Environmental Responsibility (ENSSER) welcomes the study "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" of a group of research scientists of the French Committee for Research and Independent Information on Genetic Engineering (CRIIGEN), an institutional member of ENSSER. Séralini et al. (2012) report on a two-year, full life-cycle study with rats testing Monsanto's NK603 glyphosate-tolerant GM maize (single trait glyphosate tolerance) and its Roundup co-technology in the journal *Food and Chemical Toxicology*.

The group of researchers led by Prof. Séralini has published previous toxicology studies on Roundup and its active ingredient glyphosate (Gasnier et al. 2009; Benachour et al. 2007; Benachour & Séralini 2009). The scientists also evaluated industry data submitted in support of the company's dossiers seeking approval for food/feed import. When re-analysing the developer's raw data, they found signs for toxicological effects on rat liver and kidneys after 90 days of feeding with GM maize, including the GM maize NK603 tested in this new study (de Vendômois et al. 2009; Séralini et al. 2007; Séralini et al. 2011).

Repeated calls that regulators should require more rigorous, long-term follow-up studies by the developers have consistently been ignored or rejected. Until 2011, the European Food Safety Authority (EFSA) rejected *mandatory* 90-day feeding studies as a requirement for applications for GM food and feed (European Food Safety Authority 2011). The few studies that were carried out by developers were voluntary and applied protocols of their choosing.

Main issues

1. CRIIGEN's research² was crucial in finally eliciting a policy response by the European competent authority, the European Commission's Directorate-General SANCO (Health and Consumer Safety) in 2012. In its draft Implementing Regulation on applications for authorisation of genetically modified food and feed (European Commission 2012), the European Commission stated: "toxicological studies with the whole genetically modified food and feed shall be carried out." If adopted, applicants "shall include a 90-day feeding study with whole food and feed in rodents for the assessment of food and feed containing, consisting of or produced from genetically modified plants [...]."
2. After a comparative analysis of both published industry data and the data of CRIIGEN, ENSSER concludes that many arguments which attempt to invalidate the Séralini et al. study cannot hold up to closer scrutiny. Raised criticisms are to a large extent either wrong or apply double standards. The weak point of the pilot study by Séralini et al. is the

¹ This ENSSER Statement was finalised on 04.10.2012 when the EFSA Statement was published. Therefore, the ENSSER Statement does not deal with the EFSA Statement. ENSSER will publish its analysis of the EFSA Statement in due time.

² GMO RISK EVALUATION - A Contradictory Debate, Parliamentary Workshop 2011
<http://www.ensser.org/developing-responsible-approaches-to-risk-assessment/aldeeu-parliament-workshop-2011-brussels/>

- number of animals used, which does not allow a statistical analysis of the raw data regarding one parameter measured out of over 30 - mortality. This has been acknowledged by the authors and needs to be considered/remediated in follow-up studies.
3. The controversy and vitriolic attacks evoked by the study reveal one underlying aspect: The lack of appropriate and agreed methodologies for long-term studies to scientifically assess the effects of life-time consumption of GM foods.
 4. The development of such methodology and tests, which have been demanded by concerned scientists ever since GM food was announced to be introduced into international markets, has systematically been blocked by lobby groups of industry and associated scientists. International bodies such as the Codex Alimentarius and national governments - including most EU governments and their authorities - accepted instead the concept of substantial equivalence and the concept of familiarity to evade any scientific mandatory testing of GM food for human health safety. These concepts enable authorities to easily and declare significant differences found between GMOs and their unmodified parents as 'biologically irrelevant' in an assumption-based approach without agreed methodology and thresholds.
 5. The acceptance of these industry-led, constructed models providing the conceptual justification for evading testing of food-related risks associated with the introduction of this new technology and neglecting the clearly formulated demands of European citizens led to the crisis of trust in science and regulations that now come to light with full force.
 6. Due to the proven close links between industry and EU risk assessors and the documented disproportional influence on regulations by developers and owners of the technology, it is predictable and expected that these authorities, including EFSA, will not be able to substantially revise their original assessment of GM maize NK603 (and any other application) as their credibility is at stake. These on-going conflicts of interests within EFSA have led to the European Parliament (2012) refusing the discharge of the EFSA 2010 budget as long as there is no fundamental change in policy, leadership and guidance.

1 Immediate Responses and Attacks

The publication of this study triggered orchestrated discrediting campaigns against the authors and their work, similar to previous campaigns attempting to discredit other studies finding adverse effects. This strategy has been extensively described for example in the journal *Nature* (Waltz 2009) and by Hilbeck et al. (2012). While it therefore comes as no surprise, this approach should be decried as contrary to sound scientific principles, and thus institutional anti-science. ENSSER condemns all *ad hominem* attacks and arguments and the emotional, often vicious conduct of the debate, like for example those that have gone on record in a recent article on this issue by John Vidal (2012) in the *Guardian*. Further examples are the press release by the Council for Biotechnology Information (CBI 2012) of the U.S. biotechnology industry and the business magazine *Forbes* (Miller & Chassy 2012) featuring public sector scientists and a former regulator with a long personal record of rejecting the U.N. Cartagena Protocol on Biosafety of specific GMO legislation. Miller & Chassy (2012) attack the numerous peer-reviewed publications by CRIIGEN researchers in well-respected international scientific journals: "Séralini has made a specialty of methodologically flawed, irrelevant, uninterpretable - but over-interpreted - experiments intended to demonstrate harm from genetically engineered plants and the herbicide glyphosate in various highly contrived scenarios". For those interested in reading more, we refer to the original articles for the reader to decide whether this style meets their standards.

2 Methodology and results of the Séralini et al. study

In 2010, CRIIGEN acquired external funding and set up this study to further explore the signs of toxicity observed in the experimental data of Monsanto Company. Hence, a toxicology trial was designed with the standard 10 rats per sex (total 20 for both sexes), as recommended by the revised OECD Guidelines 408 (Organisation for Economic Cooperation and Development 1998). The authors intended to repeat the work of Hammond et al. (2006) applying the Guideline 408 methodology in an extended time span. It needs to be discussed if for this purpose the number of animals should have been raised to 20 as recommended by OECD Guidelines 452 (Chronic Toxicity Studies). The authors did not apply the OECD Guidelines 451 (Carcinogenicity Studies) or 453 (Combined Chronic Toxicity\Carcinogenicity Studies) - as criticised by commentators - because the authors did not intend to conduct carcinogenicity studies because their and others previous work pointed towards toxicological but not to carcinogenic effects of certain GM foods and glyphosate-containing herbicides (Séralini et al. 2012).

2.1 Critique of scientific aspects

The most often repeated arguments by critics of Séralini et al are so far:

2.1.1 The use of Sprague Dawley rats that are prone to high natural background cancer-rates

These rats are used routinely in such studies for toxicological and tumour-inducing effects, including those 90-day studies by Monsanto as basis for the approval of NK603 maize and other GM crops (Hammond et al., 1996, 2004, 2006; MacKenzie et al., 2007). Most critical commentators of the Séralini et al. study failed to inform their readership about this fact arguing that the tumours usually develop after 3-4 month. Séralini et al. used this rat strain to keep their study design as comparable to Monsanto's as possible. Had they used another rat strain and shown adverse effects, the relevance of their results probably would have been challenged on that basis, i.e. the use of different types of rats.

Contrary to the broad claims of commentators, Sprague Dawley rats are also frequently used in long-term toxicity/carcinogenicity studies:

1. The National Toxicology Program of the U.S. Department of Health and Human Services³ uses this strain in its 2-year studies, uncontested.
2. A brief, quick and still preliminary literature search of peer-reviewed journals revealed that Sprague Dawley rats were used
 - in 36-month studies by Voss et al. (2005);
 - in 24-month studies by Hack et al. (1995), Klimisch et al. (1997), Minardi et al. (2002), Soffritti et al. (2006) and Gaméz et al. (2007);
 - in 18-month studies by Lee et al. (2010); and
 - in 12-month studies by Perry et al. (1981), Conti et al. (1988), Morcos & Camilo (2001), Flamm et al. (2003) and Gutiérrez et al. (2011).

Four of these studies had been published in *Food and Chemical Toxicology*.

³ <http://ntp.niehs.nih.gov/?objectid=72015DAF-BDB7-CEBA-F9A7F9CAA57DD7F5>

2.1.2 Food uptake not quantified

Food was offered *ad libitum* in the Séralini et al. rat studies, as is also often done, for example in the above-mentioned industry studies serving as the basis for GM crop approvals. Hammond et al. (2006) - the Monsanto feeding study for approval of NK603 - also did not measure daily food-intake during the trial to establish the amount of toxins ingested. In addition, Monsanto's Technical dossiers assessed by EFSA for food and feed approval of GM maize MON88017 and MON89034 both state "Each diet was presented *ad libitum* for approximately 90 days to 20 male and 20 female Sprague-Dawley [CrI:CD@24 (SD)] rats of approximately 6-8 weeks of age at study initiation. During the study, animals were observed twice daily for mortality and moribundity. Detailed physical examinations, including behavioural observations outside the home cage, individual body weights and food consumption were recorded weekly." This approach was accepted by EFSA and did not evoke comments by those criticising the same approach as used by Séralini et al.. Furthermore, Monsanto conducted clinical pathology evaluations on only 10 of the above mentioned 20 treated rats, the criteria for selection remained undisclosed in the Technical Dossiers. We would like to underline: the lack of quantification of the amount of toxin ingested does by no means invalidate the observed clinical symptoms.

2.1.3 Sample size too small for a long-term trial

The sample size is appropriate for 90-day toxicology trials but does not reach the number of animals recommended for long-term toxicity studies (OECD 2009). Nevertheless, the authors were able to detect significant differences in several biochemical parameters. The number of animals used is certainly too low to apply statistical tests with regard to the occurrence of tumours and mortality. The authors acknowledge that and, therefore, present the respective raw data for each individual. One possible remediation could be that the authors present their data for 1-3 months toxicity effects only and separate them from those observed afterwards.

3 Critique of disclosure policy and funding sources

Critical commentators have demanded the full disclosure of the raw data and pointed to the GM-critical stance of the financial source organisations that would provide incentives to design experimental set-ups that are more likely to detect negative outcomes. CRIIGEN announced its willingness to disclose data in the context of a fair and independent review. Again, the many calls for full disclosure as for example posted at an internet petition (Prakash et al. 2012) reveal familiar double standards. None of those experts - many of them with a long documented record of rejecting the basic principles of the EU biosafety legislation and opposing the improvement of risk assessment standards to meet these principles - were heard when data related to the applications for release and marketing of GM crops were kept secret by the regulator (on request by the applicants) and some of which could only be obtained by court decision.

Following the logic of the funding argument, which is distinct from the unrestricted disclosure point, it can be stated that it is the developers – obviously (and in principle, legitimately) pro-GM sources - which fund all regulatory trials. These are thus prone to embody methodologies or discretionary technical judgements and assumptions that will find no adverse effects. The application of this logic would invalidate all studies funded or conducted by industry and accepted by risk assessors and regulators. Clearly industrial promoters must be involved in risk assessment studies; but others funded indirectly by those interests, but not influenced

directly or indirectly by them, have to be free to perform fully independent risk assessments. This will require new institutional and perhaps legislative arrangements in regulation and science funding, and this focused debate urgently needs to be initiated, by the responsible public authorities.

4 Double standards and asymmetric scrutiny

A factual comparative analysis of the rat feeding trial by the Séralini group and the Monsanto trials clearly reveals that if the Séralini experiments are considered to be insufficient to demonstrate harm, logically, so must be those carried out by Monsanto to prove safety.

Basically, all previous studies finding adverse effects of GE crops have been treated by regulators with the attitude: only those studies showing adverse effects receive a rigorous evaluation of their experimental and statistical methods, while those that claim proof of safety are taken at face value (e.g. see also Hilbeck et al. 2012). This asymmetric scrutiny is applied by EFSA on a regular basis as confirmed in an interview with a former EFSA GMO panel member who stated: 'Of course, studies that describe potential negative environmental effects of GMOs are discussed particularly intensively' (Anonymus 2009). According to Millstone et al. (2004), this practice is interpreted by the European public as an illegitimate support for the biotechnology industry, by the supposedly impartial risk assessor. They state that "greater institutional care was taken to try to avoid false positives than to avoid false negatives. That implies that critical scrutiny has been applied in an asymmetrical fashion that prima facie seems difficult to reconcile with a precautionary approach".

A recent review by Snell et al. (2012) illustrates this same issue. In the abstract, the authors state "Results from all the 24 studies [reviewed] do not suggest any health hazards [...]" - taking all those studies at face value. Yet in their review, the authors find numerous weaknesses of similar or greater severity as raised for the Séralini group's paper. For example, of the 24 studies they evaluated 16 (67% of all studies) did not mention using the isogenic line as control (interpreted as having not used them), many did not describe the methods in any detail, and according to the reviewers had other deficiencies too. All studies that reported no adverse effects were accepted as proof of safety regardless of these manifest (but deemed irrelevant) deficiencies of their methods.

ENSSER calls for an end to these double standards and the 'shooting of the messenger' style conduct of the debate!

If the Séralini et al. study is found to be insufficient to prove harm due to methodological failings, then all previous studies submitted in support of approvals for food and feed in the EU must be reconsidered regarding their evidence for safety to human and animal health, and must be scrutinized according with the same level of rigour as is applied to such studies showing adverse effects. Likewise, a call for disclosure of all raw data by Séralini *et al.* must obviously be matched by full disclosure of all the raw data – and crucially also the biological materials at issue - by all applicants. Asymmetrical risk assessments are clearly unacceptable and comply with neither elementary standards of scientific process, nor basic standards of public propriety, nor with the precautionary principle. **The burden of proof lies clearly on the developer to demonstrate adequate evidence of safety, and not on a public re-**

search group, which is not given the necessary data, materials nor resources, to prove harm! It is difficult to resist describing this state of affairs as scandalous.

ENSSER also calls for a systematic global, comprehensive, in-depth survey and synthesis of all the anecdotal reports on record, dismissed studies, and observations from various sources (farmers, herders, veterinarians, medical staff etc) in various countries that have accumulated over the past 15 years. This survey should include ingestions/application of GM crops and of Roundup/glyphosate (evidence is accumulating that Roundup/glyphosate is far more toxic than the public and the regulators were made to believe). ENSSER could provide a list of such reports. A careful evaluation of the totality of all reports in search of potential common underlying patterns and, if so, careful evaluation of whether or not these are in agreement with the sparse reported data in the published literature from controlled experiments. A supra-national group of independent researchers / organizations should oversee this comprehensive report. Independence in this case would mean independence from the interests of the developers and IPR owners of the respective GE events and plants and of those who have a stake in this debate.

This recommendation is prudent for two reasons:

1. It would be one necessary next step to follow-up on these first data published by the group of Prof Séralini; and
2. This would for the first time since the release of this milestone report, constitute a conscientious implementation of what the collective of authors for the European Environmental Agency (2001), *Late Lessons from Early Warnings*, called for: an inclusive and diverse range of sources of multidisciplinary and experienced practitioners witnessing of possible unexpected adverse effects of such new technologies, often enacted in conditions not foreseen or tested by laboratory conditions. As the EEA volume demonstrated, such a genuinely precautionary approach does not have to imply nor be condemned as obstruction to innovation and benefit from science and technology, indeed it can stimulate new, more responsible, more scientifically informed and more socially beneficial technological trajectories.

Even the very best and most expensive, exhaustive scientific knowledge will never suffice on its own for making responsible decisions on such complex public interest matters as the approval or control of commercially promoted agricultural innovations. There will always also be normative social and ethical priorities and needs, which need to interrogate as well as be informed by the best available knowledge, and then debated and democratically decided.

ENSSER asserts that existing structures of science and policy for agricultural biotechnology and agricultural innovation and regulation more generally in Europe require an accountable and inclusive process of reappraisal and change. The key purpose of such institutional change would be to remove what are clearly anti-scientific standards and procedures, with a systematically ingrained bias against the conditions for sound independent science. In regulation and risk assessment of GM crops, egregious and blatant inconsistencies of institutional behaviour with the normative standards of sound science, which are declared and claimed for themselves by those same institutions, not only discredit science in the public arena, but discredit EU policy, and EU policy and scientific advisory institutions, too. Such change is possible – and urgent.

Statement released on 05.10.2012 at the 6th Meeting of the Parties (MOP-6) to the Cartagena Protocol on Biosafety in Hyderabad, India.⁴

⁴ more information available at: <http://www.ensser.org/>

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