

STATEMENT OF EFSA

Final review of the Séralini *et al.* (2012a) 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 Toxicology¹

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ABSTRACT

On 19 September 2012, Séralini *et al.* published online in the scientific journal Food and Chemical Toxicology a publication describing a 2-year feeding study in rats investigating the health effects of genetically modified maize NK603 with and without Roundup WeatherMAX[®] and Roundup[®] GT Plus alone (both are glyphosate-containing plant protection products). As requested by the European Commission, EFSA reviewed this publication taking into consideration assessments conducted by Member States and any clarification given by the authors. The assessments of Member States and EFSA revealed an overall agreement. The study as reported by Séralini *et al.* was found to be inadequately designed, analysed and reported. The authors of Séralini *et al.* provided a limited amount of relevant additional information in their answer to critics published in the journal Food and Chemical Toxicology. Taking into consideration Member States' assessments and the authors' answer to critics, EFSA reaches similar conclusions as in its first Statement (EFSA 2012). The study as described by Séralini *et al.* does not allow giving weight to their results and conclusions as published. Conclusions cannot be drawn on the difference in tumour incidence between treatment groups on the basis of the design, the analysis and the results as reported. Taking into consideration Member States' assessments and the authors' answer to critics, EFSA finds that the study as reported by Séralini *et al.* is of insufficient scientific quality for safety assessments. EFSA concludes that the currently available evidence does not impact on the ongoing re-evaluation of glyphosate and does not call for the reopening of the safety evaluations of maize NK603 and its related stacks. EFSA's evaluation of the Séralini *et al.* article is in keeping with its role to review relevant scientific literature for risk assessment on an ongoing basis to ensure that the advice it provides is up-to-date.

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Key words

Maize NK603, Roundup, glyphosate, experimental design, rat/rodent feeding study, toxicity, carcinogenicity

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 19 September 2012, an article was published online in the scientific journal *Food and Chemical Toxicology* that described a 2-year rat feeding study investigating the health effects of genetically modified (GM) maize NK603 sprayed during growth with or without a Roundup® (glyphosate-containing plant protection product) and of Roundup® alone. The authors of the study conclude that low levels of glyphosate herbicide formulations, at concentrations well below officially set safe limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances in rats. Similarly, they report disruption of biosynthetic pathways that may result from over expression of the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) transgene from *Agrobacterium sp.* strain CP4 in the maize NK603. The authors suggest that such disruptions may have given rise to comparable pathologies that may be linked to abnormal or unbalanced phenolic acid metabolites or related compounds.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA received a mandate from DG SANCO on 26/09/2012 requesting to address the following terms of reference (ToR) as a matter of urgency.

- (A) Review the scientific publication
- (B) Ask any clarification needed to the authors
- (C) Advise whether the publication contains new scientific elements that could lead EFSA to reconsider the outcome of its opinion on maize NK603 and its related stacks
- (D) Take into consideration the assessment of Member States
- (E) Take into consideration the assessment of the German authorities responsible for the evaluation of glyphosate

EFSA'S APPROACH TO ADDRESS THE TERMS OF REFERENCE

Following the publication of Séralini *et al.* (2012a), EFSA set up an internal task force chaired by the Director of Regulated Products (REPRO) and composed of staff scientists with expertise in biostatistics, experimental design, mammalian toxicology, biotechnology, biochemistry, pesticide safety assessments and GMO safety assessments.

EFSA decided to address the terms of reference in phases. The first EFSA Statement (EFSA, 2012) addressed ToR A, B and C solely based on the study information available through the Séralini *et al.* (2012a) publication.

The first Statement published by EFSA (EFSA, 2012) identified a number of issues that required clarification. This Statement was forwarded to Professor Séralini on the 4th October⁴, and subsequently again on the 18th October⁵ requesting these clarifications.

The task force was mandated to draft this final EFSA Statement which covers all the ToRs and is intended to take into account any information received from the authors, in addition to the assessment activities from the Member States (MSs) and the assessment of the German authorities responsible for the evaluation of glyphosate.

⁴ <http://www.efsa.europa.eu/en/press/news/121004a.htm>

⁵ <http://www.efsa.europa.eu/en/press/news/121018a.htm>

1. Introduction

In EFSA's first Statement (EFSA, 2012), the Séralini *et al.* (2012a) publication was reviewed taking into account good scientific practices such as internationally accepted reporting guidelines (Kilkenny 2010) and internationally agreed study guidelines (e.g. OECD guidelines for testing of chemicals⁶).

This final Statement takes into consideration assessments by MS institutions of Séralini *et al.* (2012a) that had been made available to EFSA and/or published prior to the finalisation of this EFSA Statement, namely Belgium, Denmark, France, Germany, Italy and The Netherlands.

The intention was to take into consideration and include the responses from the authors (i.e. study documentation and procedures followed, including the original study protocol, along with documentation on any planned or unplanned changes to it, the statistical analysis plan, the statistical report/analyses and the final full study report). At the time of publication no such reply from the authors had reached EFSA. A response from Séralini *et al.* (2012b) to criticisms of their publication was however published on-line in the journal Food and Chemical Toxicology on 9th November 2012 which has been taken into account in this final EFSA Statement.

2. Member States Reviews of the Séralini *et al.* (2012a) publication

In this section EFSA provides an overview of the assessments of the MS institutions (hereafter referred to as MSs) of the Séralini *et al.* (2012a) publication. This overview will only focus on the MSs scientific review of the Séralini *et al.* (2012a) publication. All MSs agreed to include their assessments in an Annex to this Final Statement (see Annex 1 for the full text versions and, where available, the respective mandates). Some MS mandates had included additional aspects, which are outside the remit of the EFSA mandate and therefore are not addressed in this Statement.

In line with EFSA's first Statement (EFSA, 2012), an overview of different topics is provided taking into account good scientific practices such as internationally accepted reporting guidelines (Kilkenny 2010). For each topic addressed in EFSA's first Statement (EFSA, 2012), the MSs and EFSA assessment are discussed. Where the MSs addressed scientific aspects other than those raised by EFSA in the first Statement (EFSA, 2012) this is described in section "2.6 Other issues raised by the MSs". The following assessments are considered in this final Statement:

- BE BAC Belgian Biosafety Advisory Council (BAC), 2012. Advice of the Belgian Biosafety Advisory Council on the article by Séralini *et al.* 2012 on toxicity of GM maize NK603 (WIV-ISP/41/BAC/2012_0898). Available from: http://www.bio-council.be/bac_advices.html Accessed on 20/11/2012.
- DE BVL/BfR Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), 2012. Stellungnahme des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (BVL) zu der Veröffentlichung "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" von Séralini *et al.* 2012.
 - DE BVL/BfR Bundesinstitut für Risikobewertung (BfR), 2012. Feeding study in rats with genetically modified NK603 maize and with a glyphosate containing formulation (Roundup) published by Séralini *et al.* (2012). BfR-Opinion 037/2012. Available from: <http://www.epsoweb.org/file/1095>
- DK Danish Technical University (DTU), 2012. DTU Fødevareinstituttets vurdering af nyt langtidsstudie med gensplejset majs NK603 og med sprøjtemidlet Roundup. Available from: http://www.dtu.dk/upload/institutter/food/publikationer/2012/vurdering_gmostudieseralini_okt12.pdf

⁶ Listed at http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

- FR ANSES French Agency for Food, Environmental and Occupational Health & Safety (ANSES), 2012. Opinion of the French Agency for Food, Environmental and Occupational Health & Safety concerning an analysis of the study by Séralini *et al.* (2012) “Long term toxicity of a ROUNDUP herbicide and a ROUNDUP-tolerant genetically modified maize”. Available from: <http://www.anses.fr/Documents/BIOT2012sa0227EN.pdf>
- FR HCB High Council For Biotechnology Scientific Committee (HCB), 2012. High Council For Biotechnology Scientific Committee. Opinion on the paper by Séralini *et al.* (Food and Chemical Toxicology, 2012). Available from: http://www.hautconseildesbiotechnologies.fr/IMG/pdf/HCB_scientific_opinion_Seralini_121019.pdf
- IT ISS Istituto Superiore di Sanità (ISS), 2012. National Institute of Health (ISS) assessment on the Gilles-Eric Séralini *et al.* study: “Long term toxicity of Roundup Herbicide and Roundup-tolerant Genetically Modified maize”.
 - IT IZSLT Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana (IZSLT), 2012. Technical advice concerning the study conducted by Gilles-Eric Séralini *et al.* “Long term toxicity of a Round-up herbicide and a Roundup-tolerant genetically modified maize”.
- NL NVWA, Nederlandse Voedsel-en Warenautoriteit (NVWA), 2012. Opinion of the director of the Office for Risk Assessment & Research (BuRO) concerning the assessment of the article of Séralini *et al.* (2012). Available from: <http://www.vwa.nl/actueel/bestanden/bestand/2202699>

Where English translations were not available (DK DTU and DE BVL/BfR) from the originating institution, translations were obtained through the Translation Centre for the Bodies of the European Union.

EFSA was requested by BE BAC not to explicitly refer to any of their findings in this final Statement. In the interest of openness and transparency and in agreement with BE BAC their assessment has been included in Annex 1.

2.1. Study objectives

In its first Statement (EFSA, 2012), EFSA stated that the study objectives are unclear in the Séralini *et al.* (2012a) publication. A lack of clarity in the study objectives was also mentioned by FR HCB and IT ISS & IZSLT.

2.2. Study Design

EFSA noted in its first Statement (EFSA, 2012) that Séralini *et al.* (2012a) did not follow the internationally accepted protocols for sub-chronic, chronic toxicity and carcinogenicity studies; furthermore, the strain of rats chosen is known to be prone to development of tumours over their life. The study design includes only one control group which is not suitable to serve as control for all the treatment groups. Further, it was noted that for carcinogenicity testing 10 rats per treatment group per sex is not sufficient. Apparently, no measures were taken to reduce the risk of bias such as blinding.

Overall, EFSA and MS institutions raised the same issues. Member States DE BVL/BfR, DK DTU, FR ANSES, FR HCB, IT ISS & IZSLT and NL NVWA criticised the use of such a small number of rats to draw conclusions on tumour incidence especially on a strain of rats that is highly prone to spontaneously develop tumours in their lifespan. The use of one control group for nine treated groups was considered to be inadequate by DK DTU, FR ANSES, FR HCB, IT ISS & IZSLT and NL NVWA.

2.3. Feed and Treatment Formulation

EFSA noted in its first Statement (EFSA, 2012) that details on the feed composition, the storage conditions and the presence of harmful substances (such as mycotoxins) or chemical contaminants (such as residues from glyphosate or other pesticides) were not provided. In addition, the actual exposure to GMO and/or Roundup® GT Plus (R) could not be evaluated since no food and water intakes were reported for the various treatment groups.

Member States also highlighted the lack of detail on the feed composition (DE BVL/BfR, DK DTU, FR HCB, IT ISS & IZSLT, NL NVWA), the lack of information on the presence of contaminants (FR HCB, IT ISS & IZSLT), specifically mycotoxins (DE BVL, DK DTU, IT ISS & IZSLT) and the lack of information on the actual intake of food and water (DE BVL/BfR, FR ANSES, FR HCB, NL NVWA).

Member State DE BVL/BfR highlighted that the daily applied doses of Roundup have not been determined. Member States DE BVL/BfR, IT ISS & IZSLT and NL NVWA also mentioned that further details on the composition of the applied formulations are lacking.

2.4. Statistical Methods

In its Statement (EFSA, 2012) EFSA reported that the statistical methods lacked key information, in particular, summary statistics, the unbiased treatment effect from an appropriate model and a summary of drop outs. In addition, the statistical methods used to analyse the biochemical parameters were considered to be unconventional and it was not clear if these were pre-planned.

Overall, EFSA and MS institutions raised the same issues. Member States DE BVL/BfR, FR ANSES, FR HCB, NL NVWA in addition raised the issue of the fact that multiplicity was not shown to be taken into account.

2.5. Endpoint Reporting

EFSA noted in its first Statement (EFSA, 2012) that an incomplete set of measurement endpoints was reported compared to the set of endpoints collected as reported in Seralini *et al.* (2012a). For example, the reporting of biochemical parameters, tumours and other clinical observations is incomplete.

Member States also generally highlighted the incomplete, fragmentary and selective presentation of data (DE BVL/BfR, FR ANSES, FR HCB, NL NVWA).

The attention of several MSs focused on the assessment of the tumours occurring in the experimental animals. The presentation of the data was considered by MSs DE BVL/BfR, DK DTU, FR ANSES, FR HCB, IT ISS & IZSLT and NL NVWA as being unclear. In particular the following aspects were considered to be unclear/lacking: supporting data (DE BVL/BfR), characterisation from a differential diagnostic standpoint and assessing the grade of severity (DE BVL/BfR), definitions of the groups of pathologies (DK DTU and FR ANSES, FR HCB) and histopathological characterisation of the neoplasia/animal (NL NVWA). The use of non-conventional nomenclature was addressed (FR HCB).

2.6. Other issues raised by Member States

In their Statements/opinions some MSs reported on aspects that were not mentioned in the first EFSA Statement. Those issues are reflected below.

2.6.1. Study design: choice of dose levels

Member States DE BVL/BfR and FR ANSES reflected on the lowest dose of Roundup GT Plus tested in the study and pointed out that the likelihood of finding the tested quantities in groundwater/drinking water is negligible. In addition the second dose level tested is not representative of the level to which European consumers are exposed which is far lower. The third dose level of glyphosate tested is in

line with the doses applied in practice on the field. Member State DE BVL/BfR pointed out that workers are exposed to lower dose levels and only in the short term through skin and inhalation.

2.6.2. Statistical analysis

Member States (DE BVL/BfR, FR ANSES and FR HCB) conducted statistical analyses on the tumour and mortality data that could be derived from the Séralini *et al.* (2012a) publication. They concluded that the results of their independent analyses did not support the conclusions drawn by Séralini *et al.* (2012a).

2.6.3. Interpretation of results

Member State DE BVL/BfR reported that glyphosate has been comprehensively tested and no carcinogenic effect was observed (see Section 3). The absence of carcinogenic potential of glyphosate was also mentioned by MS NL NVWA.

Member States FR HCB and NL NVWA discussed the absence of a comparison of the study results with historical control data for the chosen strain of rats. Member states DE BVL/BfR, DK DTU and FR HCB reported that mortality and tumour incidence data fall within the historical control data for the Sprague-Dawley strain of rats.

Member State DK DTU highlighted the lack of any dose-response relationship for the parameters reported as well as the “lack of a balanced scientific discussion”. Member State FR HCB, questioned the authors’ interpretation of biochemical parameters as indicators of kidney and liver failure. FR ANSES and FR HCB noted that the reported biochemical data do not establish the existence of endocrine-disrupting effects, and that the mechanistic assumptions related to modification of secondary metabolism are not supported by the results. Member States NL NVWA and DE BVL/BfR questioned the proposed endocrine mode of action for occurrence of tumours.

2.7. Member States’ conclusions

Member States DE BVL/BfR, DK DTU, FR-ANSES, FR HCB, IT ISS & IZSLT, NL NVWA highlighted that the data presented in Séralini *et al.* (2012a) do not support the conclusions drawn by the authors.

Member States DE BVL/BfR, DK DTU, FR ANSES, NL NVWA stated that the publication by Séralini *et al.* (2012) does not provide information that would indicate the necessity to reopen the risk assessment of NK603 and glyphosate while MSs FR HCB and IT ISS & IZSLT did not discuss this specific issue.

3. German authorities evaluation of glyphosate

Currently, the rapporteur MS Germany is in the process of carrying out an assessment in the context of the approval renewal of glyphosate based on Regulation (EU) No 1141/2010.

The German authority (DE BVL/BfR) reviewed the Séralini *et al.* (2012a) publication and concludes with respect to glyphosate that:

“Glyphosate has been comprehensively tested. Numerous long-term studies in rats and mice showed no indications of either a carcinogenic potential or increased mortality or any effects on the endocrine system [...]. While the performance of a long-term study in the case of the glyphosate containing formulation is in principle appreciated, it needs to be mentioned that the published study shows significant shortcomings in the study design and further shortcomings due to incomplete and unclear presentation of the collected data. Furthermore, the main statements were not supported by the experimental data. [...] it is therefore impossible to comprehend the main conclusions of the authors.”

4. Séralini *et al.* (2012b): Answers to critics

On the 9th November 2012 an accepted manuscript titled : “Answers to critics: why there is a long term toxicity due to NK603 Roundup tolerant genetically modified maize and to a Roundup herbicide” by Séralini *et al.* (2012b) has been made available on-line in which the authors provide further information about their study. In this publication no reference is made to MS assessments nor to EFSA’s first Statement (EFSA, 2012).

Below, Séralini *et al.* (2012b) is discussed in the light of all the open issues identified in the first EFSA Statement.

4.1. Study Objectives

Séralini *et al.* (2012b) state that they replicated and improved the study by Hammond *et al.* (2004) and “in order to know if the statistical findings (in 90 days) were biologically relevant or not on the long term”.

This is not reflected in the analysis and reporting in Séralini *et al.* (2012a).

4.2. Study Design

Séralini *et al.* (2012b) acknowledge that the study design is not suitable to assess long term carcinogenicity. The authors mention that the assessment of long term carcinogenicity needs to follow OECD 453 guideline with at least 50 rats per group. The authors clarify that all treatment groups contained 33% maize and give details of blinding that they implemented for some aspects of their study.

It is still unclear if there was a sample size (power) analysis conducted prior to the start of the study.

4.3. Feed and Treatment Formulation

Séralini *et al.* (2012b) state that diets were nutritionally “equilibrated” from substantially equivalent maize, and that mycotoxins were below recommended limits for food/feed. Furthermore, they refer to an assessment of diet composition, storage and diet contaminants by approved laboratories.

The feed and water consumption, and the amount of glyphosate and other used pesticides residues were however not provided.

4.4. Statistical Methods

Séralini *et al.* (2012b) do not address any of the open issues for the statistical methods as raised in EFSA’s first Statement (EFSA 2012). They state that statistical methods for the analysis of tumours endpoints cannot allow to conclude on a mortality linked or not to the treatment groups.

EFSA notes that this is inconsistent with the conclusions with respect to the tumours and mortality as drawn by Séralini *et al.* (2012a).

4.5. Endpoint Reporting

Séralini *et al.* (2012b) mention that a scientific publication is limited with respect to space and can therefore only show the data necessary to understand and discuss the conclusions, and refer to future publications that will provide more data.

It is unclear how the authors have selected the endpoints for reporting and why, for reported endpoints, the complete analysis was not provided (e.g. biochemical data were reported only for selected treatment groups, and only at one time point).

CONCLUSIONS

The review of MS and EFSA assessments revealed an overall agreement. Séralini *et al.* (2012b) in their answer to critics provided a limited amount of relevant additional information which does not address the majority of the open issues raised in the first EFSA Statement (EFSA 2012). In particular, issues such as statistical methods and endpoint reporting remain unresolved. Moreover, with regard to long term carcinogenicity and mortality, Séralini *et al.* (2012b) acknowledge that the sample size is too small to draw conclusions.

Taking all of the above into account, EFSA reaches similar conclusions, for its final review of the Séralini *et al.* (2012a) publication as in its first Statement (EFSA 2012):

Taking into consideration Member State assessments, EFSA notes that the study as described in Séralini *et al.* (2012a, 2012b) does not allow to give weight to the results and conclusions as published.

Conclusions cannot be drawn on the difference in tumour incidence between the treatment groups on the basis of the design, the analysis and the results as reported in the Séralini *et al.* (2012a, 2012b) publications. In particular, Séralini *et al.* (2012a, 2012b) draw conclusions on the incidence of tumours based on 10 rats per treatment per sex. This falls short of the 50 rats per treatment per sex as recommended in the relevant international guidelines on carcinogenicity testing (i.e. OECD 451 and OECD 453). Given the spontaneous occurrence of tumours in Sprague-Dawley rats, the low number of rats reported in the Séralini *et al.* (2012a, 2012b) publications is insufficient to distinguish between specific treatment effects and chance occurrences of tumours in rats.

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

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ANNEX 1