

## EU Denies Glyphosate Link to Cancer: German Toxicologist Accuses EU Food Safety Authority (EFSA) of Scientific Fraud

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*Dr Peter Clausing says the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA) have twisted scientific facts to give glyphosate a clean bill of health.*

*The German toxicologist Dr Peter Clausing has accused the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA) of committing scientific fraud by twisting scientific facts and distorting the truth, with the aim of concluding that glyphosate is not a carcinogen. EFSA and BfR thereby accepted and reinforced the conclusion proposed by the Monsanto-led Glyphosate Task Force (GTF).*

Clausing made this accusation in front of five judges at the Monsanto Tribunal, held in The Hague from 14-16 October.

The background to this latest allegation of foul play by the EU authorities over glyphosate is the high-level dispute over whether or not the pesticide causes cancer.



*Dr Peter Clausing at the Monsanto Tribunal*

In March 2015 the World Health Organization's cancer agency IARC concluded that glyphosate was a probable human carcinogen.[1]

BfR did not agree, stating that a classification for carcinogenicity is not “warranted” for glyphosate.[2] EFSA sided with BfR, saying that “glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential”.[3]

But Clausing told the Monsanto Tribunal that BfR’s and EFSA’s statements are contradicted by evidence contained in BfR’s own reports on glyphosate and the draft report submitted to the European Chemicals Agency (ECHA) by the German Federal Institute for Occupational Safety and Health.[4]

### Authorities twisted and distorted the truth

Clausing, a former industry toxicologist who now works for Pesticide Action Network Germany, said there is “ample evidence” that “European authorities twisted or ignored scientific facts and distorted the truth to enable the conclusion that glyphosate is not to be considered a carcinogen. The German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA) committed scientific fraud.”[4]

Clausing explained that the males of all five mouse carcinogenicity studies considered by these authorities to be of an acceptable quality showed a statistically significant increase in the incidence of one or several tumour types.

Three of the five mouse studies exhibited a significant increase in one specific type of cancer, malignant lymphoma, emphasizing the reproducibility of the finding.[4]

Clausing pointed out that these findings alone exceed the criterion for the classification of glyphosate as a 1B carcinogen (substances presumed to have carcinogenic potential for humans, largely based on animal evidence[5]) under European legislation.[6]

Europe’s pesticide regulation has a “hazard-based cut-off” clause regarding carcinogenicity,[7] meaning that a 1B carcinogen classification for glyphosate would lead to an automatic ban unless exposure was proven to be “negligible”. The law does not allow industry and regulators to argue that the doses we are exposed to are below permitted levels and therefore safe.

### Human cancer results reflect animal findings

IARC’s verdict that glyphosate is probably carcinogenic was partly prompted by what it called “limited evidence” in epidemiological studies for a link between exposure to glyphosate herbicides and non-Hodgkin’s lymphoma (NHL) in humans.

Commenting on the epidemiological studies, Clausing told GMWatch: “NHL in humans reflects the findings of malignant lymphoma in animal studies.”

Further confirmation of glyphosate’s carcinogenicity, Clausing said, comes from epidemiological studies and mechanistic evidence showing that glyphosate damages DNA and causes oxidative stress, mechanisms that can lead to cancer.[4]

### Arguments used by authorities are false or distortions

In his evidence to the Tribunal, Clausing systematically demolished arguments that the EU authorities used to dismiss the significant findings of glyphosate-induced malignant

lymphoma in mouse carcinogenicity studies.

For example, EFSA claimed, “No evidence of carcinogenicity was observed in rats and mice”.[3] But Clausen responded, “The incidence of malignant lymphoma was higher in males of all glyphosate-treated groups of all five mouse studies. In addition, a statistically significant increase occurred in three of the studies, with a clear dose-dependence in two of them.”

In another example, the German Federal Institute for Occupational Safety and Health, which based its arguments on BfR’s report, claimed that the evidence for glyphosate-induced malignant lymphoma in the animal studies was “equivocal” because of “of “lack of statistical significance in pair-wise comparison tests” or “partly contradictory study outcomes, depending on the statistical method applied”.[8]

But Clausen showed this argument to be invalid. In assessing cancer results in animal studies, the OECD, which sets guidelines for industry testing of chemicals, recommends the use of two methods of statistical analysis: trend tests and pair-wise comparisons. It prefers trend tests as the “more powerful” method. In addition, and most importantly, the OECD clearly states, “Significance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result.”

Clausen showed that the Federal Institute abused OECD guidelines in two ways:

1. It attempted to play off one statistical method against another, dismissing the significant cancer increase revealed by one method on the grounds that the other method did not show a significant increase – even though the OECD says that a significant finding from either method is enough to rule out chance as the cause.
2. In an example of bias, it chose to believe the results of the weaker method, which did not find a significant cancer increase.

The Federal Institute appears to have done this in order to hide the finding that glyphosate caused increased cancer in the rats.

Why did IARC disagree with the German authorities?

Interestingly, the IARC reviewed the available animal studies and concluded, like Clausen, that they showed that glyphosate caused an increase in cancer. Why the difference of opinion between IARC and the German authorities?

The answer is given in BfR’s own report on IARC’s findings.[10] Unlike the German authorities, IARC applied the superior statistical analysis – the trend test. Also unlike the German authorities, IARC did not violate OECD guidelines by claiming that a second type of statistical analysis cancelled out the findings of the first.

BfR accused of intentionally falsifying science on German TV

The statistical dodge employed by the German authorities to defend glyphosate was the subject of an explosive in-depth news report that aired on German TV last October,[11] in the midst of deliberations by EU authorities on whether to re-authorize the chemical.

The news report was broadcast by MDR, which is part of ARD, the main public national TV network in Germany. The report says that BfR stands “accused of endangering the

population” and shows BfR director Prof Andreas Hensel facing questions from experts before the German Parliamentary committee for food and agriculture.

One of the experts, Prof Dr Eberhard Greiser, a retired epidemiologist at the University of Bremen, says of BfR’s actions, “I’d say this is an intentional falsification of the content of scientific studies.”

The MDR film notes that BfR, in its initial report to the EU authorities, claimed that there were no signs of cancer in the animal studies: “They took the position that even though one of the five studies on mice did show a significant increase in malignant lymphoma, they dismissed it as irrelevant, because, the BfR asserted, the other four studies did not indicate any cancer risk.”

But then, says the film, the “bombshell” hit, in the form of IARC’s report stating that glyphosate was a probable human carcinogen.

The IARC experts had seen something different from BfR in the animal studies they looked at. In one lifetime study in mice they saw significant increases in kidney tumours, and in another, increases in blood vessel cancer. They also noted increases in malignant lymphoma in glyphosate-treated animals in a further three studies in mice.

However, these three studies were only mentioned in the IARC report; they were not included in the final evaluation and classification of glyphosate because the IARC experts did not have access to the full dataset. That is because these were industry studies, the details of which are kept hidden from the public and independent scientists under commercial confidentiality agreements with regulators. It is a fundamental principle of IARC to confine its evaluations to evidence that is in the public domain and where it has access to the full dataset.

Under pressure from the IARC report, BfR produced an “Addendum”[2] to its initial report, in which it defended its conclusion against the IARC findings. BfR now admitted that all of the tumour findings mentioned by IARC – and in additional studies – were significant, but explained them away by using the statistical dodge described above, along with other scientifically questionable practices described by Clausen in his evidence to the Tribunal.

MDR’s report featured Green politician Harald Ebner expressing surprise that the BfR still stood by its overall conclusion that there is no cancer risk from glyphosate, despite the new evaluation of the studies.

Ebner says, “I’m kind of stunned. Yes the studies are not new, they are a few years old. Then I ask myself, ‘How can they overlook them until now? Why did the BfR previously conclude that they were not significant, no carcinogenic effects?’”

Shockingly, the MDR investigation revealed that BfR did not perform its own statistical analysis of the industry test results: “The BfR literally said that they relied on the manufacturers’ reports. Does this mean that they accepted those reports at face value?”

This is the conclusion of Peter Clausen, who was interviewed by the MDR film makers after a painstaking evaluation of the BfR reports. Clausen says in the film: “The German Federal Institute for Risk Assessment has confirmed several times in writing that it performed an independent evaluation of the studies and materials it had. That should include the statistical evaluation of cancer studies. And the fact that the results of the industrial studies

were so blindly trusted is scandalous.”

Taken together, Clausing’s evidence to the Tribunal and the MDR film raise serious questions about BfR’s and EFSA’s scientific integrity and competence. It’s no surprise that EU member states have so far failed to agree to re-authorize glyphosate. In response to the impasse, the Commission has granted a temporary 18-month re-licensing of glyphosate rather than the usual 15 years to give the “competent” agencies time to deliberate and pass a final judgment. It will be interesting to see how BfR’s growing credibility crisis affects the verdict.

#### Notes

1. IARC (2015). IARC Monographs Volume 112: Evaluation of five organophosphate insecticides and herbicides. <http://monographs.iarc.fr/ENG/Monographs/vol112/>
2. RMS Germany (2015): Renewal Assessment Report Glyphosate. Addendum 1 to RAR, Assessment of IARC Monographs Volume 112 (2015): Glyphosate, 31 August 2015. <http://bit.ly/2eMJ8KG>
3. EFSA (2015): Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302.
4. Clausing, P. Regulatory agencies (BfR, EFSA) used biased arguments to deny the carcinogenicity of glyphosate: Memorandum by Dr Peter Clausing, PAN Germany, as a witness to the Monsanto Tribunal. The Hague, Netherlands, 15-16 October 2016. [http://www.pan-germany.org/download/Memo\\_Monsanto-Tribunal\\_Peter\\_Clausing\\_10\\_2016.pdf](http://www.pan-germany.org/download/Memo_Monsanto-Tribunal_Peter_Clausing_10_2016.pdf)
5. CNRS Chemical Risk Prevention Unit (PRC) (2011). Carcinogens, mutagens, reproductive toxicants: European regulatory classification criteria, hazard communication elements. CNRS. <http://www.prc.cnrs-gif.fr/IMG/pdf/cmr-criteria-clp.pdf>
6. Regulation EC 1272/2008.
7. Regulation EC No 1107/2009.
8. German Federal Institute for Occupational Safety and Health (2016). Proposal for Harmonised Classification and Labelling. Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance Name: N-(phosphonomethyl)glycine; Glyphosate (ISO). ECHA. [http://echa.europa.eu/documents/10162/13626/clh\\_report\\_glyphosate\\_en.pdf](http://echa.europa.eu/documents/10162/13626/clh_report_glyphosate_en.pdf)
9. OECD (2012). Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453, 2nd Edition Series on Testing and Assessment No. 116. ENV/JM/MONO(2011)47, Paris. [http://www.oecd.org/officialdocuments/displaydocument/?cote=ENV/JM/MONO\(2011\)47&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocument/?cote=ENV/JM/MONO(2011)47&doclanguage=en)
10. RMS Germany (2015). Renewal Assessment Report Glyphosate. Addendum 1 to RAR, Assessment of IARC Monographs Volume 112 (2015): Glyphosate, 31 August 2015. p. 37. <http://bit.ly/2eMJ8KG>
11. Investigative reporter Andreas Rummel’s film was broadcast in Germany by Mitteldeutscher Rundfunk (MDR) in October 2015. The film (in German) is included in Rummel’s glyphosate herbicides dossier on MDR’s website: <http://www.mdr.de/fakt/glyphosat156.html>  
Direct link to the film: <http://www.mdr.de/fakt/video-57628.html>

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