

Bundesinstitut für Risikobewertung (BfR) • Postfach 12 69 42 • 10609 Berlin

Der Präsident

Maria Noichl
Member of the European Parliament
Rue Wiertz 60, ASP 12G152
B-1047 Brussels
cc: EFSA, Dr. Jose Tarazona and Dr. Bernhard Url
cc: UBA, Ms Maria Krautzberger
cc: Members of the Agricultural Committee of the
German Bundestag
cc: Dr. Stefan Weber and Dr. Helmut Burtscher-
Schaden

Professor Dr. Dr. Andreas Hensel
Bundesinstitut für Risikobewertung
Postfach 12 69 42
10609 Berlin
Tel. +49 30 18412-3000
leitung@bfr.bund.de
www.bfr.bund.de

Ihre Zeichen und Nachrichten vom

29.01.2019

Gesch.-Z.: Bitte bei Antwort angeben

50-0202-04/004-10357260

Tel.-Durchwahl/Fax

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Datum

11.02.2019

Study “Detailed Expert Report on Plagiarism and superordinated Copy Paste in the Renewal Assessment Report (RAR) on Glyphosate”

Dear Ladies and Gentlemen,

We acknowledge your letter of 29 January 2019. We regret your concern but do not share it. On the contrary, the grounds for your concern give rise to concern of a more fundamental nature with us and the other European assessment authorities.

It is of course the duty of members of parliament to ask critical questions about the actions of authorities, to draw attention to the possible exertion of influence and lobbyism and to make these a topic of public discussion. This is unarguably in the best interests of a democratic society and consumer protection.

It is neither appropriate nor helpful, however, to disregard the scientific results of all European assessment authorities. We observe with concern that the public discussion of scientific findings is currently being dominated by political or ideological desires and perceptions and that science is being shifted more and more into the background.

The purpose of our reply is therefore to focus more on the actual facts of the matter, as the reputation of our independent and impartial institution, which works conscientiously in the interest of public health, is being questioned and compromised.

We resolutely defend ourselves against all attempts to deliberately damage the reputation of the BfR – as in the case of the so-called “plagiarism study” – and to portray it in public as untrustworthy, lazy, incapable or corruptible.

Scientific results should be the focus of discussion

Your allegations are based on a computer-supported text comparison of an in-house document prepared within the scope of the European reapproval process for glyphosate. The critical debate with the scientific results and the conclusions drawn from them should be the central issue of any discussion here. Instead, we are currently arguing about the percentages of our own formulations and those of others on the basis of a computer-supported text comparison. This is all the more astounding as we are not even disputing that the text of some passages of the reviewed documents is identical. The sole factor which is decisive for scientific assessment is whether the text correctly conveys the scientific assessment status or not. If the latter is the case, nothing is taken over, neither text nor content.

Independent risk assessment stands at the centre of our scientific work

All of the people involved in the process at the institutions in question are civil servants funded by the taxpayer, so whether a plant protection product is authorised or not is of no consequence for the necessary assessment work we perform as scientists before a decision is reached. Our independence guarantees a risk assessment based on scientific facts.

It may well be that you regard the legal regulations as inadequate and see a need for improvement here, but you should not blame those whose legal remit it is to execute them. We follow the legal regulations established by the parliaments with which the state fulfils its commitment to consumer protection.

Study results: The quality decides

We use the best available methods to assess the effects of substances on human health. We are also one of the few authorities that conduct independent research in addition to this. In no way did we take over the views of the applicants and their interpretation of studies without criticism and without reviewing them. In line with our legal remit, it goes without saying that we assess the originals of all studies. All evaluations of these studies made by the applicants are also comprehensively and critically assessed by us from a scientific point of view. And by the experts of the other member states too, by the way, who subject our draft assessments to further review.

The sole criterion for the consideration of study results is the quality and evidence of the original studies with their raw data and the scientific publications. The possible interests of applicants, politics or other interest groups can and may not play any role in a scientific assessment. Our primary goal is to focus public perception more on the scientific contents, because we also have the legal remit to communicate risks independently.

We find it extremely disquieting that you topicalise the opinion of "plagiarism hunters" in your letter, thus indirectly accusing a federal authority and representatives of EU authorities of not complying with applicable EU law. This is a serious allegation which is entirely dishonest against the background of a total lack of evidence. We would have hoped for and expected more knowledge of official procedure here.

Reports from industry are automatically included in assessment reports

In the field of toxicological assessment, it was and still is customary when making European comparisons to copy parts of the applicants' dossier into the assessment report. Our sister institutions, such as the French institution ANSES and the Swedish authority, also work in this way. The *Bayerischer Rundfunk* broadcaster recently made this a topic of its "investigative research". Do you therefore seriously want to accuse the heads of all scientific assessment authorities in Europe of having broken EU law? That would be absurd.

A text can only be plagiarism if it is capable of being plagiarised, but this is not the case with these assessment reports. In this regard, it is amazing that the expert report you quote deals with a document which is unsuitable for the purpose of plagiarism checking. Reports from industry are a legally prescribed basis for the assessment reports. Our assessment report is an official document in an administrative process which serves the purpose of making a comparison of the scientific facts produced by experts of the approval authorities and is therefore not capable of being plagiarised either.

This procedure is explained several times on the website of the European Food Safety Authority (EFSA), by the way, where Dr. Bernhard Url, head of EFSA, states that: *"It is natural and necessary that parts of the company's dossier appear in sections of the draft assessment report prepared by the rapporteur member state."* It must therefore be regarded as being very much a customary practice.

It is prescribed in the legal procedures for the health assessment of plant protection products, biocidal products, drugs and numerous other chemicals that manufacturers must conduct a defined spectrum of experimental tests at their own expense. In addition to these studies in the original with their raw data, the assessment authorities must also be presented with a summarising dossier, which also contains evaluations of the applicant on published scientific literature. Furthermore, third parties including NGOs submitted additional publications and the BfR also conducted its own literature research several times. Internationally recognised standard toxicological procedures such as those of the OECD have to be taken into account when reviewing the studies. The assessment of the studies and freely accessible scientific publications have to be included and listed in the assessment reports prepared by the authorities. We verify all original studies and documentation submitted by industry very conscientiously.

All available studies were assessed independently

You write that 90% of the content of the chapters in the BfR report in which the published literature on the health risks of glyphosate is assessed was in actual fact written by the Monsanto-managed GTF without any indication being given to this effect. This is wrong.

We quote from the chapter in the BfR report in which the published literature on the health effects of glyphosate is assessed:

"For higher efficiency of the review and for the sake of transparency, the descriptions of methods and study results in the GTF dossier were virtually not amended and even the conclusions were kept as provided. However, each study that is described in detail was com-

mented by RMS. These remarks on (the) bottom of each study description are clearly distinguished from the original submission by a caption and are always written in italics."

The procedure used by the BfR is therefore outlined in all clarity. Our remarks at the end of the study descriptions differ clearly from the original submission of the applicant.

You write that the procedure used by the BfR had the consequence that independent scientific studies which describe the carcinogenic and DNA-damaging effects of glyphosate were seen as completely irrelevant or unreliable and were not given further consideration. This is not correct either. The BfR considered and assessed all available studies and publications.

It must be pointed out here from a professional point of view that in many of the studies and publications discussed among scientists with regard to possible carcinogenicity and genotoxicity, as well as epidemiological findings, glyphosate was not isolated, i.e. treated as a pure substance, but rather was only used in the formulation as a standard product along with various other components. As the toxicity of the formulants can be higher than that of the active substance glyphosate and the exact composition is not always given in articles published in scientific journals, the validity of studies of this kind with agents containing glyphosate is scant with regard to the testing of active substances within the scope of the EU approval process.

Consent among international assessment authorities

We at the BfR are in agreement with all EU assessment authorities and many other authorities all over the world that according to the latest available knowledge, glyphosate does not have a genotoxic or carcinogenic effect. These include by way of example the European Food Safety Authority, the European Chemicals Agency and the American environmental authority, as well as the assessment authorities from Canada, Australia, Japan and New Zealand.

The computer-supported text comparisons were made on the wrong document

If someone is of the opinion that the conclusions of the European assessment authorities and European Food Safety Authority regarding the carcinogenic potential of glyphosate should be doubted, so-called plagiarism checks should be made on the document in question. The document checked by the "plagiarism hunters", the Renewal Assessment Report (RAR), is the wrong document, however. The RAR should be viewed in a certain sense as the first draft of the official assessment report. It was available for comment to the other EU authorities and any interested parties among the general public. The final RAR was prepared on the basis of the comments. When assessing glyphosate, Germany was required to completely revise once again the part of the report on carcinogenicity and genotoxicity in an addendum, taking into account the assessment of the International Agency for Research on Cancer (IARC). This agency was not involved in the consultation process. The final document for the European risk assessment is the EFSA Conclusion of 2015.

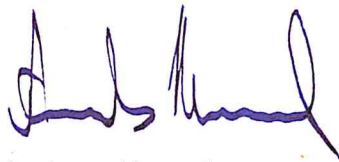
Presentation of the reports is being further improved

In order to avoid misunderstandings in public perception, the BfR as one of the leading scientific institutions among the assessment authorities suggested optimizing the presentation

of the work of the authorities. The current procedure was therefore changed in order to further increase the transparency of the reporting. The fundamental *modus operandi* of the BfR, i.e. the critical review of all original data and studies, is not affected by this. It is merely an optimisation of the presentation for the benefit of any interested parties in the general public. A new citation practice must of course become obligatory in this case. This new procedure is mandatory for the BfR as a new working instruction.

We hope that we have introduced some clarity to the debate with these remarks. It goes without saying that we are open to further suggestions and discussions.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Andreas Hensel', with a stylized, cursive script.

Andreas Hensel

A handwritten signature in blue ink, appearing to read 'Reiner Wittkowski', with a stylized, cursive script.

Reiner Wittkowski