

Independence and quality assurance of the European glyphosate assessment

BfR communication No 002/2019 on the draft health assessment of glyphosate (RAR) of 14 January 2019

The members of the special committee “EU Approval Process for Pesticides (PEST)” published their draft of the final report in December 2018. Since then, the BfR has been receiving repeated inquiries, especially about the independence of the scientific institutions and the procedure for assessing the active substances contained in plant protection products.

The sole criterion for the consideration of study results is the scientific quality and evidence of the studies. Possible interests of the party commissioning the study, politics or other interest groups can not and must not play any role in a scientific assessment. For this reason, the BfR and European assessment authorities did not make use of certain overview articles often referred to as the “Monsanto Papers” as a basis for assessment, preferring instead to validate the original listed studies. The impartiality and independence of the BfR are anchored in German law. The BfR was established on 1 November 2002 to conduct independent, unbiased scientific risk estimations and strengthen consumer protection. The Institute welcomes the current discussions and efforts being made to achieve more transparency in pesticide legislation.

The BfR had already prepared the first draft of the health assessment of glyphosate (Renewal Assessment Report, RAR) in 2013. The RAR is a draft for assessment in a European regulatory administrative procedure and an in-house document which has been subjected to several peer reviews and to public consultation. This is done for all EU plant protection product approval procedures. The final document for the European assessment of glyphosate is the EFSA Conclusion of 2015. The final version contains all comments, including those made by scientists not involved in the process, as well as non-governmental organisations before being published by EFSA. This report, which all assessment institutions of the EU member states have adopted, was the essential foundation for the decision of the EU Commission to extend the glyphosate approval.

<https://www.efsa.europa.eu/de/efsajournal/pub/4302>

The BfR has again compiled a list of the most frequently asked questions (FAQ) and their answers. Many of the questions refer only to the preliminary draft (RAR).

The answers given by the BfR to questions from members of the European Parliament on the subject of glyphosate can be accessed using the following link:

http://www.europarl.europa.eu/cmsdata/147095/Answers%20Hensel%20BfR_DE.pdf

Links to already published FAQ on the process of the re-assessment of glyphosate and the hearing “Monsanto Papers and Glyphosate” can be found at the end of this document.

What is the Renewal Assessment Report on the health assessment of glyphosate (RAR)?

The German Renewal Assessment Report (RAR) on glyphosate was a preparatory work for the European Food Safety Authority (EFSA) from 2013. The RAR is an in-house document which is merely a draft and which was subjected to several peer reviews and public consultation. The final document for the European assessment of glyphosate is not the RAR but rather the EFSA Conclusion of 2015 (<https://www.efsa.europa.eu/de/efsajournal/pub/4302>).

The federal government appointed the Federal Office of Consumer Protection and Food Safety (BVL) as the leading authority for the RAR in Germany. The RAR was then revised on the basis of comments in peer reviews made public before being thoroughly checked, commented upon and comprehensively discussed by EFSA and experts from the responsible authorities in the member states. After the International Agency for Research on Cancer (IARC) had published its monograph in 2015, this assessment was critically reviewed by the BfR once again in an addendum to the RAR in which the original studies were evaluated yet again.

The BfR addendum on the IARC report and not the RAR then became the decisive basis for assessing carcinogenicity and mutagenicity as the assessment of the German authorities. This was then discussed with all member states, as well as the IARC, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the United States Environmental Protection Agency (US-EPA) and the European Chemicals Agency (ECHA) at a meeting of experts. The result of this consultancy then became the basis for the EFSA Conclusion.

Did the BfR adopt parts of the applicants' studies on glyphosate approval without review or criticism?

No. The procedure for assessing the active substances contained in plant protection products, such as glyphosate, is regulated by legislation that applies throughout the EU. This legislation explicitly stipulates that the rapporteur member state – Germany in the case of glyphosate – must examine all of the information contained in the documents submitted by the applicants for plausibility and correctness. If the rapporteur member state concurs with a particular summary or assessment of an applicant, it can integrate this directly into its report. Deviating assessments are expressed by adding comments. The rapporteur member state then prepares a comprehensive, independent assessment of the applicants' proposals and includes its own assessment of the safety of the active substance.

The BfR is legally obliged to use and review the dossiers of the applicants before making its own independent assessment. In no way did the BfR subscribe to the applicants' point of view and its interpretation without examination or criticism. In its report, the BfR made use primarily of the legally prescribed studies and reports of the applicants, along with other relevant and available studies and publications, in order to add support after they had all been carefully examined and assessed in compliance with the legally established procedures.

What are the "Monsanto Papers"?

The BfR is not aware of any uniform definition of the "Monsanto Papers". The term is applied in public discussion to documents containing the internal communications of an applicant, as well as to publications in scientific literature alleged to have been influenced by Monsanto.

Why did the BfR not take the Monsanto Papers into account in its assessment?

Legal requirements constitute the essential basis for active substance assessment by the member states. These do not include the so-called "Monsanto Papers", which are review articles that summarise published original studies. This does not exclude the possibility, however, that the BfR does not also include review articles as a component of the publicly accessible literature in the assessment documents. The BfR assessment, on the other hand, is based on the data reported in original studies, several of which were also subsequently listed in the Monsanto Papers, which had no influence on the decision to classify genotoxicity. These include the following publications, for example: Williams et al. 2000, Kier & Kirkland 2013, Greim 2015.

How controversial is the conclusion in the scientific community that, according to the latest available information, glyphosate should not be classified as carcinogenic to humans?

Just like the BfR, the European Food Safety Authority (EFSA) and other authorities all over the world, the WHO committee responsible for pesticide assessment (JMPR) concluded that, as far as can be established from the latest available information, no carcinogenic risk to humans is to be expected if the product is used for its intended purpose in a proper manner. Furthermore, the European Chemicals Agency (ECHA) independently established that a hazard classification with regard to carcinogenicity, mutagenicity and reproduction toxicity is not warranted. The International Agency for Research on Cancer (IARC) has proposed that glyphosate be classified as “probably carcinogenic to humans”. IARC evaluations are usually adopted by the Californian EPA. One of the reasons for the different classifications could be that, in line with its statutes, the IARC only considers published studies. This would mean that many of studies required by law for the EU approval process and thus paid for by industry had not been published at that point in time were therefore not available to the IARC.

Which institutions arrived at the conclusion that glyphosate should not be classified as carcinogenic and genotoxic in accordance with the latest available knowledge?

The following competent authorities concluded that glyphosate is not be classified as carcinogenic and genotoxic in accordance with current knowledge.

- The European Food Safety Authority (EFSA) and experts of the risk assessment authorities of the EU member states
- The American Environmental Protection Agency (US-EPA)
- The Canadian Pest Management Regulatory Agency (PMRA)
- The Australian Pesticides and Veterinary Medicines Authority (APVMA)
- The Japanese Food Safety Commission
- New Zealand's EPA environmental authority
- The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and
- The European Chemicals Agency (ECHA)

How does the BfR ensure the independence of its scientific assessments?

The BfR assures the quality of its work. Scientific risk assessment with regard to human health is an official task which is performed exclusively by civil servants and employees subject to collective salary agreements without the assistance or advice of any external persons, such as representatives of trade and industry, associations or companies. These assessments are conducted without the involvement of any kind by the BfR committees. Neither does the BfR receive financial support of any kind from private institutions, nor enter into cooperation with them. No funding is raised from trade and industry for reasons of independence, nor does the BfR become financially involved in research projects of this kind.

Why are some passages from submitted original studies and documents integrated into the assessment reports?

The quality of the work performed by the BfR is officially assured in line with the corresponding guidelines and templates of the European Commission and/or European Food Safety Authority (EFSA), as well as internal procedural and work instructions. The BfR reporting system has been altered in recent years in line with amended technical guidelines and internal work instructions.

After the scientific review of all documents presented by the applicant, certain passages of the submitted original studies and documents can be integrated into the assessment reports, but the conclusions to these studies are always drawn by the BfR itself. The extent of the text passages adopted from the study reports or the applicants dossiers depends on each specif-

ic test area at the BfR. Thus, for example, studies with a plant protection product are usually described in a separate section by the BfR and text passages from the applicants dossiers are only adopted once they have been examined and found to be correct by the BfR. The same applies to the area of exposure estimation and risk assessment for users, workers, residents and bystanders, as well as the field of analytics.

The European assessment authorities do not consider it to be either scientifically necessary or resource-efficient to re-write **simple** study descriptions (especially in the area of material and methods and inclusion of tables) in the approval process of the active substances contained in plant protection products with regard to toxicology and residues if the applicants have presented the studies correctly or interpreted them correctly in terms of science and methodology in corresponding summaries. Possible errors, inaccurate or incomplete study descriptions were mentioned.

Has the procedure for presenting and the assessment of the data in the assessment reports been refined since it was introduced in 1995?

Yes. The BfR has proposed the optimisation of the presentation of the work of the authorities in order to avoid misunderstandings in the perception of the general public. The current revised procedure was altered for this reason in order to further increase the transparency of reporting. The fundamental approach 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 in the interests of the public.

The requirement to further improve the comprehensibility of the official assessment reflects the response of the authorities to the increasing public interest in these documents. The BfR welcomes the increased interest in an expanded social dialogue and – in collaboration with the other authorities – has actively and transparently adapted the presentation form of the scientific basis necessary for this exchange in its assessment reports.

How is the available scientific literature reported in the assessment reports?

It is the responsibility of the assessment authorities to check that the applicants have conducted a literature search in compliance with legal requirements and presented an overview of the entire literature in line with their legal obligations. Whether and to what extent the literature search presented by applicants is complete has to be examined in detail through independent research conducted by experts from the rapporteur member state. In the case of glyphosate, the BfR researched the literature independently and identified a number of more recent publications which had not yet been published at the time the application was made. The relevance and reliability of the published studies must be assessed in a separate process.

Were passages from the assessment report for initial approval also included in the RAR?

In the course of the re-approval process, the BfR included several passages from the assessment report for initial approval in the RAR after subjecting them to critical review. This complies with the standard procedure of the authorities and the agreed principles of international scientific assessment institutions. It goes without saying that the BfR made a scientific evaluation of the data on which they were based. The conclusions from these studies were always drawn by the BfR itself.

The assessments of all of the studies published in scientific journals were not conducted by BfR personnel. Is that correct?

No. The BfR conducted a scientific review of the primary data. The conclusions to these studies were always drawn by the BfR itself. Nevertheless, the BfR proposed the optimisation of the presentation of the work of the authorities in order to avoid misunderstandings in the perception of the general public. The current revised procedure was altered for this reason in order to further increase the transparency of reporting. The fundamental approach 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 in the interests of the public.

More information on the subject of glyphosate at the BfR website

Frequently asked questions about the “Monsanto Papers and Glyphosate” hearing at the European Parliament on 11 October 2017

<https://www.bfr.bund.de/cm/349/frequently-asked-questions-about-the-monsanto-papers--and-glyphosate-hearing-at-the-european-parliament-on-11-october-2017.pdf>

Press release: Glyphosate assessment: BfR rejects plagiarism accusations of 20 September 2017

http://www.bfr.bund.de/en/press_information/2017/34/glyphosate_assessment_bfr_rejects_plagiarism_accusations-201890.html

Press release: Unfounded allegations against scientific assessment authorities of 5 October 2017

http://www.bfr.bund.de/en/press_information/2017/40/unfounded_allegations_against_scientific_assessment_authorities-203462.html

Press release: European assessment of glyphosate was conducted with quality assurance and independently of 11 October 2017

http://www.bfr.bund.de/en/press_information/2017/41/european_assessment_of_glyphosate_was_conducted_with_quality_assurance_and_independently-202097.html

FAQ on the procedure for the re-assessment of glyphosate within the framework of the EU active substance review of 12 November 2015

<http://www.bfr.bund.de/cm/349/frequently-asked-questions-on-the-procedure-for-the-re-assessment-of-glyphosate-within-the-framework-of-the-eu-active-substance-review.pdf>

FAQ regarding the different estimations of the carcinogenic effect of glyphosate by BfR and IARC of 11 December 2015

<http://www.bfr.bund.de/cm/349/frequently-asked-questions-regarding-the-different-estimations-of-the-carcinogenic-effect-of-glyphosate-by-bfr-and-iarc.pdf>

FAQ on the assessment of the health risk of glyphosate of 1 March 2016

<http://www.bfr.bund.de/cm/349/frequently-asked-questions-on-the-assessment-of-the-health-risk-of-glyphosate.pdf>

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany.

It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.