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

BfR FAQ of 13 October 2017

During the "Monsanto Papers and Glyphosate" hearing at the European Parliament in Brussels on 11 October 2017, the BfR received questions, the most frequently asked of which have now been compiled into these FAQ.

At the end of this document you will find links to FAQ that have already been published on the reapproval process of glyphosate, on the divergent evaluations of the carcinogenic effect of glyphosate made by the BfR and International Agency for Research of Cancer (IARC) and on the assessment of the health risks of glyphosate.

How disputed among scientists is the result that, according to the latest level of available knowledge, glyphosate is not to be classified as carcinogenic to humans?
The WHO committee responsible for the assessment of pesticides (JMPR), like the BfR, the European Food Safety Authority (EFSA) and other authorities all over the world, comes to the conclusion that, in accordance with the latest level of scientific knowledge, no risk of a carcinogenic effect in humans is to be expected if the substance is used properly and for its intended purpose. In addition to this, the European Chemicals Agency (ECHA) established independently that a hazard classification with regard to carcinogenicity, mutagenicity and reproduction toxicity is not called for. The International Agency for Research of Cancer (IARC) recommended that glyphosate be classified as "probably carcinogenic to humans". This evaluation is not currently shared by any other national scientific assessment authority anywhere in the world. One of the reasons for the divergent evaluations could be that according to its statutes, IARC only takes published studies into account. This means that many studies which are legally required within the scope of the EU approval process but which have not yet been published were not available to IARC.

Which institutions come to the conclusion that glyphosate should not be classified as carcinogenic according to the latest level of available knowledge?
After making their own assessments using established, internationally recognised standard toxicological methods, every single assessment authority in Europe and throughout the world which had access to the original studies arrived at the conclusion that in line with the current level of available knowledge, glyphosate should not be classified as carcinogenic.

These include:

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

Why is the reapproval of glyphosate being discussed?
Just like every other plant protection product active substance, glyphosate is reassessed with regard to the risks it poses to the health of humans, animals and the environment, as well as its effectiveness at regular intervals within the scope of EU active substance testing. The Federal Republic of Germany was commissioned as the Rapporteur Member State (RMS) for glyphosate by the European Commission. In the reapproval process, the BfR was commissioned with the assessment of the health risks posed by the active substance, as well as a sample formulation in compliance with its responsibility in line with plant protection legislation.

Who was involved in the preparation of the assessment report?
The assessment of glyphosate was made by the BfR and other German authorities such as the Julius-Kühn Institute (JKI), Federal Environment Agency (UBA) and Federal Office of Consumer Protection and Food Safety (BVL). Germany, as the rapporteur member state, made its Renewal Assessment Report (RAR), including its subsequently prepared addenda, available to the European Food Safety Authority (EFSA) as the coordinating authority for further procedural steps.

Why was the BfR not present at the joint hearing of the Committee on Agriculture and Rural Development and Committee on the Environment, Public Health and Food Safety at the European Parliament on 11 October 2017?
The basis for the impending political decision on the reapproval of glyphosate is essentially the assessment report prepared by the European Food Safety Authority (EFSA). The contents of this report were presented at the hearing by the EFSA itself. The BfR had offered to participate in the public hearing at the EU Parliament if there proved to be any special need to do so.

Did the BfR take over any parts of the applicants' studies on glyphosate approval without review or criticism?
No. The process for assessing plant protection product active substances like glyphosate is regulated by legislation that is valid throughout the EU. This legislation expressly stipulates that the rapporteur member state - in the case of glyphosate, Germany - must examine all of the information contained in the documents submitted by the applicants for its plausibility and correctness. If the rapporteur member state concurs with any summary or assessment made by the applicants, it can integrate these directly into its report. Deviating assessments are expressed as separate comments. The rapporteur member state prepares a comprehensive, independent assessment of the application made by the applicants and includes its own assessment of the safety of the active substance.

The BfR is legally obliged to use and review the dossiers submitted by the applicants when making its own assessment. The BfR did in no way adopt the view of the applicants and their interpretation of the corresponding studies without criticism or review. In its report, the BfR primarily used the legally prescribed studies and reports of the applicants to support its views, as well as all other relevant and available studies after all of them had been carefully reviewed and assessed in accordance with the legally established processes.

What are the "Monsanto Papers"?
The BfR is not aware of any uniform definition of the "Monsanto Papers". In the public discussion, documents used for the internal communication of an applicant, as well as publications in scientific literature that were allegedly influenced by Monsanto, have been designated as the "Monsanto Papers".

Why did the BfR not take the "Monsanto Papers" into account in its assessment?
Legal requirements form the essential basis for the assessment of active substances by the member states. These do not include the so-called "Monsanto Papers", which are synoptic overview studies summarising original studies that have already been published. The assessment of the BfR, on the other hand, is based on the data reported in original studies, several of which were subsequently listed in the so-called "Monsanto Papers" too.

Were several significant accumulations of tumours detected in animal studies caused by glyphosate?
The evaluation of findings made using animal experiments in toxicological studies requires special expertise. The European authorities evaluated the experimental studies on rodents not only with regard to their statistical significance, they also assessed all of the available data using a weight of evidence approach, which was published in the ECHA guidelines as well as by the EFSA Scientific Committee (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971/epdf). In this approach, the results of all methods for evaluating the results of animal studies are included and assessed along with other findings. The most important lines of evidence include background contamination, historical controls and OECD recommendations on limit doses, as well as various statistical comparisons with reference to dose-response ratios, the consistency and reproducibility of effects and plausibility with a mechanism of action. In doing so, existing uncertainties are also taken into account. The result of this was that every single European assessment authority came to the conclusion that neither the studies with rats nor with mice give any indications of any carcinogenic or mutagenic effects with relevance for humans.

How does the BfR ensure its independence when making scientific assessments?
The BfR uses a quality assurance system in its work. Scientific risk assessment where human health is concerned is an official task which is performed exclusively at the BfR by civil servants and salaried employees without any help or advice from outsiders, such as representatives of trade and industry, associations or companies. These assessments are made without any kind of involvement of the BfR committees. The BfR does not receive any financial contributions of any kind from private institutions, nor does it enter into any cooperation arrangements with them. For reasons of independence, no funding is accepted from industry, nor does the BfR participate financially in research projects of this kind.

More information on the topic of glyphosate at the BfR website

Press release: Glyphosate assessment: BfR rejects plagiarism accusations. 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. 5 October 2017 (German only)
http://www.bfr.bund.de/de/presseinformation/2017/40/haltlose_vorwuerfe_gegen_wissenschaftliche_bewertungsbehoerden-202011.html

Press release: European assessment of glyphosate was conducted with quality assurance and independently. 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 process of reassessing glyphosate within the scope of EU evaluation of active substances. 12 November 2015
http://www.bfr.bund.de/en/frequently_asked_questions_on_the_procedure_for_the_re_assessment_of_glyphosate_within_the_framework_of_the_eu_active_substance_review-195637.html

FAQ on the divergent estimations of the BfR and IARC regarding the carcinogenic effect of glyphosate. 11 December 2015
http://www.bfr.bund.de/en/frequently_asked_questions_regarding_the_different_assessments_of_the_carcinogenic_effect_of_glyphosate_by_bfr_and_iarc-195635.html

FAQ on the assessment of the health risk posed by glyphosate. 1 March 2016
http://www.bfr.bund.de/en/frequently_asked_questions_on_the_assessment_of_the_health_risk_of_glyphosate-127871.html

About the BfR
The German Federal Institute for Risk Assessment (BfR) is an independent scientific research institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). It advises the Federal Government and Federal States on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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