

## Glyphosate: BfR has reviewed and assessed the original studies of the applicants in depth

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In response to the inquiries regarding the Renewal Assessment Report (RAR) on glyphosate, the German Federal Institute for Risk Assessment (BfR) would like to explain the legally prescribed procedure. Individual reports in the media have suggested that the BfR copied its assessment from authorisation applications of the applicants. In reality, however, the BfR has painstakingly and in detail reviewed and assessed under its own responsibility both the legally required studies of the applicants as well as all other relevant and available studies.

For the sections in the RAR pertaining to analytical monitoring methods, toxicology, metabolism and the residue assessment, the BfR assessed all the studies and publications submitted by the applicants, as well as studies published in scientific journals, which were researched by the BfR.

The legally prescribed procedure for the approval of active substances on EU level explicitly stipulates that the applicants must submit study summaries. For reasons of transparency, the BfR also outlined the detailed study descriptions and the assessments of the applicants in Volume 3 of the RAR – for the original toxicological studies – but added its own critical comments (in italics). As a result, the reader can determine whether the BfR and the applicants arrived at the same or differing assessments in the case of each individual study. In other words, the BfR lists its own, independent assessments of the relevance, scientific quality and validity of all of these studies and publications in accordance with the legal stipulations. The independent health assessment of the BfR for the entirety of the studies submitted by the applicants and for the researched literature can be found in Volume 1.

In the renewal procedure, the German Federal Institute for Risk Assessment (BfR) was commissioned to assess the health risk of the active substance glyphosate. This assessment was the initial part of the European approval procedure, which was independently peer reviewed by the experts of the member states and the European Food Safety Authority (EFSA) in a transparent assessment process, and confirmed the basic statements made by the BfR.

During the public and expert consultations of EFSA on glyphosate, the comments of the scientific community, the public, the policymakers, industry and non-governmental organisations were incorporated in the process in line with the procedure established on EU level that governs all active substances. The assessments in the RAR on health and environmentally relevant risks were thoroughly reviewed, commented on and discussed in depth by EFSA and experts from the competent authorities of the member states. In the EFSA Conclusion, the majority of the European experts also confirm the health assessment of the German Federal Institute for Risk Assessment (BfR) stating that, when used correctly and in line with its intended purpose in agriculture, glyphosate is not expected to pose any carcinogenic, mutagenic or reprotoxic risks. EFSA has published its Conclusion on its website together with other documents including the RAR.

Following their own assessments using established, internationally recognised, standard toxicological methods, all assessment authorities worldwide who had access to these original data have reached the conclusion that glyphosate should not be classified as carcinogenic based on current knowledge.

These authorities include:

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

### 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.

### More information on the topic of glyphosate on the BfR website

[http://www.bfr.bund.de/en/a-z\\_index/glyphosate-193962.html](http://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html)



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