Frequently asked questions on the procedure for the re-assessment of glyphosate within the framework of the EU active substance review

BfR FAQ, 12 November 2015

Active substances used in pesticides are subject to approval by the European Commission. Following the first application, this approval is limited to a maximum period of 10 years. Before the end of this period, the manufacturers must apply for renewed approval if they want to continue to use this active substance in pesticides. Once the application has been filed, the active substance is re-assessed. Within the framework of the approval procedure, the Commission appoints a member state to act as Rapporteur Member State (RMS). In the case of glyphosate, the Federal Republic of Germany was named RMS. The German government appointed the Federal Office of Consumer Protection and Food Safety (BVL) as the lead authority for the drafting of the Renewal Assessment Rapport (RAR).

In the re-assessment procedure, the Federal Institute for Risk Assessment (BfR) was commissioned to assess the health risk of the active substance and one representative formulation.

BfR has prepared questions and answers on the procedure for the re-assessment of the active substance glyphosate within the framework of the EU active substance evaluation.

What is the significance of the re-assessment of glyphosate within the framework of the EU evaluation of active substances?

Like any other active substance in a pesticide, glyphosate is regularly re-assessed within the framework of the EU evaluation of active substances to determine the risk to health and the environment as well as its efficacy. Germany is the Rapporteur Member State (RMS) for the Community evaluation and assessment of glyphosate. In the re-assessment procedure, BfR was commissioned to assess the health risk of the active substance and one representative formulation. The legally required documents were submitted by a coalition of several applicants known as the Glyphosate Task Force (GTF). In addition, the European Food Safety Authority (EFSA) issued a public call to make documents and data available for the assessment of glyphosate and incorporated the received documents in the procedure.

What is the timetable for the procedure?

The first draft of the assessment report based on the GTF application documents and BfR's own literature research was compiled up to the end of 2013 in line with the timetable stipulated by the European Commission and forwarded by the Federal Office of Consumer Protection and Food Safety (BVL) to the European Food Safety Authority (EFSA). The report comprises the findings of the work performed by BfR, which assesses the health risk for humans and animals, as well as the reports of the Federal Environmental Protection Agency (UBA; investigation of impacts on the environment) and the Julius Kühn Institute (investigation of efficacy and impacts on the health of bees).

The consultation with the experts from the other member states and the applicants took place at the beginning of 2014 in a peer review process, as did a public consultation under the lead management of EFSA. The German authorities involved in the process then incorporated the comprehensive comments and additionally supplied studies from the consultation process with the member states and the interested members of the general public in the revised overall report and submitted the report as requested to EFSA in December 2014.

Following a consultation with the experts of the member states at EFSA in February 2015, some questions remained that needed to be addressed. BfR sent all the requested additional findings to BVL on 1 April 2015, who then forwarded the revised overall report to EFSA.

Following the publication of the monograph by the International Agency for Research on Cancer (IARC) on the classification of glyphosate as "probably carcinogenic to humans, carcinogenic in Group 2A" at the end of July 2015, BfR was commissioned by the German government and EFSA to review this assessment by IARC. BfR completed this review during the month of August 2015 and forwarded its report to the Federal Office of Consumer Protection and Food Safety (BVL) in the form of an addendum to the Renewal Assessment Report. BVL passed the German assessment on to EFSA. During the month of September 2015, EFSA organised a peer review on the addendum and an additional expert meeting of the member states. This meeting was also attended by representatives of the World Health Organisation (WHO), IARC and the United States Environmental Protection Agency (USEPA). As a result, it was possible to take account of the IARC assessment in the re-assessment of glyphosate within the context of the EU active substance review. Based on the revised RAR and the addendum, the experts at EFSA prepared the summarised report (EFSA Conclusion) for the assessment of glyphosate for the purpose of renewed approval. This completed the scientific assessment process in the approval procedure.

Who decides whether to extend the approval for glyphosate in the EU?
The European Food Safety Authority (EFSA) has drawn up a recommendation (Conclusion) for the European Commission based on the revised overall report including the addendum on the IARC monograph, and forwarded this recommendation to the EU Commission and the member states at the end of October 2015. In consultation with all European member states, the EU Commission will decide on the approval or renewed approval of the active pesticide substance glyphosate. Only approved active substances are then subjected to a zonal authorisation procedure for all requested pesticides and approved in each individual member state.

On which sources did BfR base the health assessment of glyphosate?
In addition to the original studies and documents submitted by the applicants in line with the legal regulations, BfR also made use of all available published studies as well as other sources in its scientific assessments. In addition, the documents received in response to a public call issued by the European Food Safety Authority (EFSA) to make documents and data available for the assessment of glyphosate were used in the BfR assessment process.

Is it problematic within the context of the approval procedure that BfR takes sources into consideration that come from or were financed by the industry?
The legal procedure in Europe stipulates that the applicant must perform and pay for the toxicological studies for the requested active substance. This corresponds to the general principle used in other approval procedures - such as those under the pharmaceutical laws - that the producer or distributing company bears responsibility for the safety of the products and must also prove their safety. The studies must be performed in line with Good Laboratory Practice (GLP) and the OECD guidelines on the toxicological testing of chemicals as well as EU Test Method Regulation No. 440/2008. The guidelines also stipulate the number and type of animals to be used, for example, as well as the control groups for the toxicological end points to be investigated in each case.

The sole criterion for the inclusion of study findings is the scientific quality and evidence of the studies. Possible interests of those commissioning the studies, political interests or interests of other stakeholders cannot and may not play any role in a scientific assessment.

The analysis of sources submitted by the applicants in the industry (Glyphosate Task Force) is part and parcel of the legally prescribed assessment process.

Which criteria are used to assess the sources used?
BfR assesses scientific findings for the regulatory approval and licensing procedure solely on the basis of the scientific quality and evidence of the studies and data on which these findings are based. The criteria for evaluation of scientific quality are the OECD guidelines on the toxicological testing of chemicals and the EU Test Method Regulation No. 440/2008. The latter defines in detail how the tests are to be performed. In addition, the legal regulations in Europe stipulate that the required studies must be conducted in accordance with the rules of Good Laboratory Practice (GLP). All other sources that do not meet these requirements but have been published in scientific journals are also incorporated in the assessment process. The criteria used are published in technical guidelines of the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), which are currently being updated.

How is the quality of the assessment assured?
Various measures ensure that the assessment process by the authorities is transparent and logically structured: BfR operates an externally audited quality management system. The EU approval procedure also provides for various quality assurance measures, including the involvement of the other EU member states and the public. The public consultation gave the general public as well as other EU member states the chance to issue their comments on the report on the re-assessment of glyphosate in advance and to submit further studies. Widespread use was made of this option. During the revision of the report, BfR reviewed and took account of all comments and recommendations.

Did BfR take some of the assessments of the industry on board?
No. All the sources on which the assessment report is based were - as is the case with all other health risk assessments - evaluated solely by BfR staff. The health assessment of BfR draws exclusively on the original studies or on articles published in the scientific literature.

In its assessment report, BfR included the **summary** of the information on the experimental procedure and the findings of the Glyphosate Task Force (GTF) only for the toxicological studies - not for the studies on analysis, residue assessment and application safety. During this process, errors and redundancies were corrected and a separate BfR assessment was presented in the revised assessment report in a specially highlighted paragraph. As a result, the report and the assessment of active substance toxicology were clearly separate.

This means that BfR conducted its own assessment of each study or literature publication and did not rely on summaries compiled by the industry. BfR also conducted a fully independent risk assessment based on the hazard assessment and exposure estimate, and described this assessment once again in the form of a summary for the re-assessment of glyphosate in Volume 1 of the report, as stipulated by European law for every assessment of active substances in pesticides. The independent nature of the BfR risk assessment is reflected by, among other things, the differing assessments and conclusions arrived at by BfR and GTF.

What say does the "BfR Committee for Pesticides and Their Residues" have in the risk assessment of glyphosate?
The "BfR Committee for Pesticides and Their Residues" is not involved in the statutory tasks of BfR. In other words, it has no say in the assessment of substances in line with the legal remit of BfR.

BfR draws on the external expertise of the BfR Committee in order to take account of the current status of scientific and technological knowledge as well as the practical knowledge that exists in other institutions in the ongoing conceptual development of assessment concepts or the involvement of BfR in the drafting of technical guidelines.

The issues dealt with by the BfR Committee for Pesticides and Their Residues are outlined in the meeting minutes published on the BfR website:
http://www.bfr.bund.de/de/bfr_kommission_fuer_pflanzenschutzmittel_und_ihre_rueckstaende-11084.html

Which comments from the public were included in the revised assessment report?
BfR reviewed the scientific quality and evidence of all comments and information from the public in the revised assessment report and took them into consideration accordingly.

Did BfR also commission its own studies in connection with the re-assessment of glyphosate?
Yes, BfR also commissioned its own studies for the purpose of re-assessment. The numerous evaluated documents showed, for example, that the toxicity of certain pesticides containing glyphosate can be higher than that of the active substance itself due to the co-formulants they contain, such as tallowamines as surfactants. We therefore conducted in-vitro analyses and used molecular biology methods to investigate the toxicity of mixtures in order to develop alternatives to animal experiments. In addition, BfR initiated a research project conducted by the University of Veterinary Medicine Hannover which investigated the influence of a pesticide containing glyphosate and tallowamines on the metabolism and microbial population of the reticulum in ruminants for the first time. The findings of this study show that the active substance glyphosate and the co-formulants have no negative effect on the microflora of the reticulum. There are also no indications that bacteria of the Clostridium species breed more readily under the influence of glyphosate.

How are other published glyphosate studies taken into account in regulatory decisions?
University laboratories also conduct toxicological studies with active pesticide substances, usually for research purposes or on behalf of third parties. These kinds of studies are also taken into consideration in the scientific assessment and are assessed based on the same criteria with regard to quality and evidence.

How were the comments from the public consultation process incorporated in the BfR report on the health assessment of glyphosate?
BfR revised the assessment report to take account of the comments received from the member states, EFSA, the Glyphosate Task Force (GTF) and the public consultation.

All the documents subsequently requested from the GTF by the BfR were incorporated, as were articles from scientific journals that had not previously been taken into consideration or were only published last year. Overall, BfR reviewed and assessed 350 individual comments and notes (including those from individual persons and non-governmental organisations) and, where necessary, took them into account in the revision of the assessment report.

The number of incorporated literature references was significantly increased, and the scope of the sections on the detection of glyphosate in human urine, oxidative stress, epidemiological studies and the effects on farm animals was considerably expanded. The information on carcinogenicity and mutagenicity was also supplemented. Even if a higher intake via the skin is now assumed for the representative formulation (a pesticide containing the active substance glyphosate), there is no change in the fundamental assessment of the active substance.

In its assessment, did BfR neglect to take account of publications on carcinogenic effects due to glyphosate, as a result of, among other things, oxidative stress?
BfR reviewed, commented on and assessed all the studies named in these allegations (including those on oxidative stress) and incorporated these studies in the revised assessment report or the addendum. These additionally considered studies do not provide any scientific indication of a causal relationship between exposure to the active substance and an increased risk of cancer for humans. One of the reasons for this is that the necessary data sheets, dose data or transparent details regarding the substances that were actually tested are missing in some of the studies.

Is the revised assessment report confidential?
No. Following completion of the assessment of glyphosate on European level and the forwarding of the Conclusion of the European Food Safety Authority (EFSA) containing the assessment of the experts from EFSA and the European member states to the EU Commission and the EU member states, EFSA will publish the revised assessment report of the Federal Republic of Germany including the addendum on the IARC monograph on its website.