

The BfR has made a comprehensive check of the epidemiological studies on glyphosate

There is no divergence between the BfR and IARC with regard to the limited indications of the carcinogenicity of glyphosate in humans.

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The renewal approval process for the active substance glyphosate follows the same procedural rules and principles of a common European approval process directed by the EU Commission as those which also apply to all other active pesticidal substances. In the current EU active substance approval process for glyphosate, the Federal Institute for Risk Assessment (BfR) has thoroughly reviewed and evaluated all available studies on a sound scientific basis. These also included the epidemiological studies quoted by the International Agency for Research on Cancer (IARC) in its monograph. Not only the BfR but also the assessment authorities of the EU and other countries, as well as the IARC, arrive at the conclusion that these studies provide only limited indications of the carcinogenicity of plant protection products containing glyphosate (mixtures of the active substance and formulants). They are of little relevance for the assessment of the pure active substance glyphosate ("limited evidence in humans"). The BfR recommends that the discussion of the assessment of epidemiological studies be continued on a scientific level.

Within the scope of the EU active substance review, the European Food Safety Authority (EFSA) published the first German assessment report on glyphosate from December 2013. By doing so, the EU member states and the general public had the opportunity from April 2014 to comment on the German assessment report on the re-evaluation of glyphosate and submit additional studies. Extensive use was made of this opportunity. When revising the report, the BfR reviewed all of the comments and recommendations with regard to their scientific quality and evidence and gave them due consideration in the revised assessment report of December 2014, among other things by including new epidemiological and mechanistic studies.

The BfR already took the core epidemiological studies into account in the renewal assessment report (RAR) of April 2015. In the addendum of August 2015, the BfR assessed additional studies that the IARC had listed. With regard to the conclusions on epidemiology, in which the BfR fundamentally concurs with the IARC, these additional studies do not result in any change to the overall assessment.

In the addendum of August 2015, all of the studies quoted in the IARC monograph of July 2015 were assessed once again. By doing so, the first draft from 2013 was comprehensively revised as the basis for the decision of the EU Commission in the commenting and quality assurance process initiated by the EFSA.

In this way, all of the available studies were reviewed and assessed on a solid scientific basis and with the utmost care and attention in the final documentation and mutual evaluation in the current EU active substance approval process for glyphosate.

On the basis of **epidemiological studies** on humans, the IARC concludes that "there is limited evidence in humans for the carcinogenicity of glyphosate". Just like the IARC, the BfR considers the three other IARC categories ("evidence suggesting lack of carcinogenicity", "inadequate evidence of carcinogenicity" and "sufficient evidence of carcinogenicity") to be inapplicable for classifying the results of the human studies. Under consideration of the pub-

lic consultations that were conducted, the assessment of the epidemiological studies by Germany as the Rapporteur Member State complies with the assessment of the IARC. The BfR would like to point out that the epidemiological studies presented to date cannot in principle differentiate between the effects caused by glyphosate and those caused by plant protection products (mixtures of the active substance and formulants) or the formulants themselves.

In the epidemiological studies, the effect of glyphosate is not examined as an isolated active substance, i.e. as a pure substance, but rather in various mixtures as a conventional plant protection product with several other components. As the toxicity of the formulants can be higher than that of the active substance glyphosate and the exact composition is often not described in publications in scientific journals, the significance of studies on plant protection products containing glyphosate is low in comparison to the testing of the pure active substance within the scope of the EU approval process.

If the active substance is again approved, all studies on each individual formulation – including all epidemiological studies as well – will be included in the assessment during the subsequent approval process of plant protection products containing the active substance glyphosate in the EU member states. As a result, it will then be possible for each individual preparation to make a concrete distinction between the effects caused by the active substance glyphosate and those caused by plant protection products or formulants. In the result of its assessment, the BfR expressly recommends that additional examinations of plant protection products containing glyphosate which either exonerate or confirm the findings made to date should be called for within the scope of the national/zonal approval of each individual plant protection product.