

BfR reviews monograph of the International Agency for Cancer Research (IARC) on glyphosate - divergence procedure within the WHO still in progress

BfR Communication No. 024/2015 of 30 July 2015

Following a review of all available studies, glyphosate, an active substance used in pesticides, has been assessed as non-carcinogenic for humans by the competent national, European and other international institutions for health assessment including the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) based on the current data and the assumption of intended uses. The International Agency for Cancer Research (IARC) of the World Health Organization (WHO) recently classifies glyphosate as a carcinogenic substance in Group 2A, in IARC words "Probably carcinogenic to humans", based on the available and evaluated studies by IARC. This classification was initially published in a short report in the "Lancet Oncology" journal on 20 March 2015 but was not explained scientifically in detail. The full report on glyphosate from the IARC monograph (Volume 12) has been publicly available since 29 July 2015, and the Federal Institute for Risk Assessment (BfR) is reviewing the monograph with regard to documentation that was previously not taken into account, the assessment findings, quality aspects and methodology. Germany – as the rapporteur member state for the active substance glyphosate within the framework of active substance approval - is also forwarding the findings to EFSA and ECHA. The WHO itself has set up an "ad hoc expert task force" to compare the publications considered by its own bodies IARC and the JMPR to identify new studies to clarify the reasons for the different assessments. This process is known as a scientific divergence procedure within the WHO. In addition, the German government has commissioned the BfR to conduct a scientific review of the IARC monograph.

With regard to a potential carcinogenicity of glyphosate, IARC concludes that there is only limited evidence for Cancer in humans. IARC states that the available epidemiological studies provide only limited evidence of a statistical connection between exposure to glyphosate and an increased risk of non-Hodgkin lymphoma, a neoplastic disease of the lymphatic system. In its classification, IARC points to findings of carcinogenicity studies as sufficient evidence for cancer in experimental animals. These findings are also evaluated by the BfR and have already been assessed in the revised assessment report (RAR) in the context of the EU active substance evaluation procedure. This report was submitted in December 2013 to EFSA and was as part of the public consultation process in April 2014, which means that IARC also had access to these studies and the draft conclusions.

Many of the studies on possible carcinogenicity and genotoxicity that are currently the subject of discussion in the scientific world do not use the pure active substance glyphosate but only as part of a formulation, in other words in the form of a commercially available product together with various other components, such as co-formulants and together with other active substances. Especially, as the toxicity of the co-formulants may be higher than that of the active substance glyphosate, and as the exact composition is frequently not described in published articles in scientific journals, the informative value of the studies that used agents containing glyphosate is sometimes low with regard to the active substance evaluation within the framework of the EU approval procedure.

The fact that different bodies assess issues or methods differently due to differing information and assessments of experimental data is part and parcel of the scientific risk assessment process.

The BfR has enclosed a preliminary assessment of the short publication of IARC concerning the potential carcinogenic effect of glyphosate in its revised report and has recommended that a renewed approval process for glyphosate should take account of a detailed assessment of the IARC monograph.

(<http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf>)

EFSA is to assess the findings of a report by the IARC which concludes that the herbicide glyphosate is probably carcinogenic to humans.

<http://www.efsa.europa.eu/en/press/news/150730.htm>

The BfR is currently also requested by EFSA to review the classification published by IARC and will first complete its review of this scientific assessment by IARC before issuing its comments.

The WHO Taskforce should compare the publications considered by IARC and those considered by the JMPR, identify those that have not been considered by either IARC or JMPR and should consider whether newly available genotoxicity studies provide evidence that any of the compounds could be genotoxic. The Taskforce should report back to JMPR in September 2015 for further discussion and action.

More information:

Glyphosate FAQ

http://www.bfr.bund.de/en/frequently_asked_questions_on_the_health_assessment_of_glyphosate-127871.html

Glyphosate in the A-Z index of the BfR

http://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html

BfR-contribution to the EU-approval process of glyphosate is finalised

<http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf>