

No cancer risks concealed: All professional conclusions reached by the BfR have been publicly accessible for years

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The German Federal Institute for Risk Assessment (BfR) is currently receiving inquiries about a scientific paper prepared by the Institute on the active substance glyphosate which was published on an internet platform without the consent of the BfR.

The paper in question is a German language summary of Addendum I drafted by the BfR in 2015. Addendum I and all professional conclusions have been publicly accessible since autumn 2015: <https://www.efsa.europa.eu/de/press/news/151119-0>.

The BfR makes reference to copyright law regarding this course of action. In no way were any cancer risks concealed. This course of action is independent of the scientific assessment.

The BfR sent the paper to an applicant on the basis of an inquiry made in line with the Freedom of Information Act. The BfR simultaneously asserted its copyright on the paper, however. As a basic principle, third parties may not publish the work of another party without the consent of that party. The BfR was therefore exercising its rights as a scientific institution. This course of action is of fundamental significance for the future scientific activities of the BfR.

The Regional Court of Cologne (*Landgericht Köln*) ruled in March 2019 that the BfR document may no longer be made available on the internet platform for the time being. Additional inquiries in line with the Freedom of Information Act are currently being received, all of which the Institute will examine.

The BfR has compiled some frequently asked questions on the subject.

Is the BfR trying to conceal cancer risks?

No. All professional conclusions can be freely accessed by the general public since autumn 2015. The BfR makes reference to copyright law regarding this course of action. This course of action is independent of the scientific assessment and scientific contents.

Why did the BfR assert its copyright?

As a basic principle, third parties may not publish the work of another party without the consent of that party. The authors of the paper are scientific employees of the BfR. As a scientific opinion constitutes an act of intellectual creativity by a scientific institution, copyright is the prerogative of that institution.

In doing so, the BfR exercises its rights as a scientific institute. This course of action is of fundamental significance for a federal authority involved in scientific work which provides political advice.

To which decisions on copyright issues can the BfR refer?

The BfR makes reference to the publicly accessible decision of the Regional Court of Cologne (LG Köln, 15.12.2016 - 14 O 302/15) and Higher Regional Court (*Oberlandesgericht*) of Cologne (OLG Köln, 06.12.2017 - 6 U 8/17) in the temporary injunction proceedings BfR vs MDR. These are published in the juridical database 'Juris', for example. The federal state

of North Rhine-Westphalia also offers a research service via the link <https://www.justiz.nrw/BS/nrwe2/index.php>. The decisions can also be accessed here by entering the corresponding reference number. The principle proceedings are currently still pending.

How many inquiries in line with the Freedom of Information Act (FOIA) have been received by the BfR to date and how will the BfR deal with them?

As of 3 April 2019, more than 23,000 standardised inquiries have been received. The BfR is currently checking how the inquiries can be processed in a technically efficient manner. Maintenance of the capacity to perform scientific tasks has top priority here. Whether and to what extent applicants will be charged a fee in accordance with the FOIA can only be decided once the applications have been processed.

What role does the supervisory ministry (BMEL) play?

The BfR is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL). As a public law institution, the BfR represents itself in court or commissions a law office to do so if this is prescribed by law. It notifies the supervisory ministry (BMEL) accordingly. The BfR is independent in its scientific assessments, research and communication.

Why did the BfR not publish the paper itself?

Addendum I and the summarising paper in German were not published by the BfR in 2015 because they were part of the European approval process for glyphosate. The paper in question is a German language summary of a document (Addendum I) drawn up by the BfR in 2015. Addendum I was published in autumn 2015 by EFSA as the authority in charge of the process. All professional conclusions can therefore be accessed by the public. The German summary does not provide any new scientific facts.

Addendum I and the German summary of the BfR paper are still the subject of a current legal dispute before the Regional Court of Cologne dealing with fundamental questions concerning the BfR's copyright. The BfR will decide on publishing the summarised paper once the proceedings have been concluded.

Should studies on the active substances contained in plant protection products within the scope of approval proceedings be publicly accessible in the opinion of the BfR?

The BfR has been advocating more transparency in the assessment process for years. Original toxicological studies prepared by industry should be freely accessible in the same way that the assessment reports published by EFSA already are. The applicable laws must be heeded here, however.

Unrestricted public access to scientific information is desirable in the view of the BfR. Glyphosate has been assessed as non-carcinogenic by the BfR in line with the latest available knowledge. This decision was reached on the basis of an independent and comprehensive evaluation of all available scientific studies. After making their own assessments, all assessment authorities worldwide which had access to the original data concluded that, in accordance with the latest available knowledge, glyphosate should not be classified as carcinogenic to humans.

Which institutions currently conclude that glyphosate should not be classified as carcinogenic to humans?

After making their own assessments using established, internationally recognised standard toxicological methods, the following assessment authorities in Europe and throughout the world conclude that glyphosate is not carcinogenic and genotoxic with regard to its effects on humans in accordance with the latest available knowledge.

- The German Federal Institute for Risk Assessment (BfR)
- The European Food Safety Authority (EFSA) and experts of the risk assessment authorities of the EU member states
- The American Environmental Protection Agency (US-EPA)
- The Canadian Pest Management Regulatory Agency (PMRA)
- The Australian Pesticides and Veterinary Medicines Authority (APVMA)
- The Japanese Food Safety Commission
- New Zealand's EPA environmental authority
- The Joint FAO/WHO Meeting on Pesticide Residues (JMPR), UN Food and Agriculture Organisation (FAO) and World Health Organization (WHO)
- The European Chemicals Agency (ECHA)

More information on the subject of glyphosate at the BfR website:

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



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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.

This text version is a translation of the original German text which is the only legally binding version.