

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

BfR Communication No. 021/2019 of 07 June 2019

The German Federal Institute for Risk Assessment (BfR) is currently receiving applications for information 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 synoptic opinion prepared by the BfR in response to the IARC monograph on glyphosate of 4 September 2015. The detailed scientific assessment contains Addendum I, which was also drafted by the BfR. Addendum I and all professional conclusions have been publicly accessible since autumn 2015:

<https://www.efsa.europa.eu/de/press/news/151119-0>.

By way of a general ruling, the BfR decided to place the synoptic opinion at the disposal of all applicants individually via a BfR website which cannot be accessed by the general public. By doing so, the Institute fulfils its obligations in accordance with the Freedom of Information Act on the one hand while maintaining its copyright on its scientific work results on the other.

The BfR sent the paper to an applicant at the end of 2018 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. These legal issues are of fundamental significance for the future scientific activities of the BfR. This course of action is independent of the scientific assessment. In no way were any cancer risks concealed during the reassessment of the active substance glyphosate

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.

### **What is the synoptic opinion?**

It's a six-page summary written by the BfR in German on the IARC monograph about glyphosate of 4 September 2015. This opinion is not an expert assessment. The detailed scientific evaluation is contained in Addendum I, which was also written by the BfR in 2015. Addendum I and all expert conclusions have been available for free public access since autumn 2015: <https://www.efsa.europa.eu/de/press/news/151119-0>

### **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 opinion are scientific employees of the BfR. As a scientific paper constitutes an act of intellectual creativity by a scientific institution, copyright is the prerogative of that institution. The work of the BfR is distinguished by its scientific, research-supported approach through all areas of its expertise. Against this background, it is of fundamental significance for the BfR to establish who has the right of first publication to its intellectual property. The current legal disputes are intended to clarify this matter.

### **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 is the BfR dealing with them?**

As of 5 June 2019, more than 43,000 standardised inquiries have been received. By way of a general ruling, the BfR decided to place this opinion at the disposal of all applicants individually via a BfR website which cannot be accessed by the general public. The general ruling of 23 April 2019 was published in the Federal Gazette on 3 May 2019 ([https://www.bundesanzeiger.de/ebanzwww/wexsservlet?page.navid=to\\_official\\_part](https://www.bundesanzeiger.de/ebanzwww/wexsservlet?page.navid=to_official_part)). The information can be accessed in written form at a web portal (<https://dokumente.bfr.bund.de/glypo/>) provided at this special website. Log-in is enabled by individually mailed access data and is possible multiple times within a period of seven days. By doing so, the Institute is fulfilling its obligations in accordance with the Freedom of Information Act on the one hand while maintaining its copyright on its scientific work results on the other. The BfR is embarking on this new course in order to satisfy legal requirements with regard to the transparency of decisions made by authorities and to reply to inquiries within an appropriate period of time. No fees are charged for accessing the information.

### **What costs has the BfR incurred for the creation of the web portal?**

The BfR did not commission any company with the creation of the portal. The costs of utilising its own personnel were not charged separately. Total expenditure was subsequently estimated to be less than 15,000 euros.

### **Why did the BfR not mail the document?**

Sending it per post to all applicants would have involved huge costs for paper, printing, postage, personnel etc. This would not have been appropriate either with a view towards natural resources. Mass e-mailing was ruled out too as it would have increased the risk of further copyright infringements.

### **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 opinion itself?**

Addendum I and the opinion in German were not published by the BfR in 2015 because they were part of the European approval process for glyphosate. 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.

Addendum I and the summary of the BfR opinion are still the subject of current legal proceedings before the Regional Court of Cologne dealing with fundamental questions concern-

ing the BfR's copyright. The BfR will not publish the opinion during the proceedings as the entitlement to first publication could not then be clarified by the court. The BfR will decide on publishing the summarised opinion 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#fragment-2](https://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html#fragment-2)



BfR "Opinions App"

## 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.*