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Federal Ministry
of Food
and Agriculture

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taz.die tageszeitung
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Open Letter to the Editor-in Chief of *taz.die tageszeitung*

Dear Mr. Löwisch,

While we respect and appreciate the duty of the press to point out the exertion of political influence and lobbyism to its readers in the best interest of consumer protection, it is to no one's benefit if it is based on allegations rather than facts.

I found a number of inconsistencies in the article "In the Swamp of the Lobbyists" of 30 December 2016 in the taz from Le Monde Diplomatique. These could have been avoided if you had researched the concrete facts of the matter directly with us, as should be expected of normal journalistic practice.

I have taken the following statement from the article: "*The manufacturers of the pesticides, i.e. the applicants, are allowed to decide for themselves in the authorisation of a new pesticide in which EU country the assessment is to take place, which is doubtless why the decision was reached in favour of Germany when the task in hand concerned the most important EU re-approval of a substance in recent years: glyphosate.*"

The connection made here is false. What is correct is that the EU Commission appointed Germany as the Rapporteur Member State. As the testing of glyphosate involved the renewal of approval of the active substance, the manufacturer could not select the rapporteur member state, as claimed in your article. The correct account is to be found on the BfR website.[1]

[1] Frequently asked questions on the procedure for the re-assessment of glyphosate within the framework of the EU active substance review, BfR FAQ of 12 November 2015
http://www.bfr.bund.de/cm/349/frequently-asked-questions-on-the-procedure-for-the-re-assessment-of-glyphosate-within-the-framework-of-the-EU-active-substance-review.pdf

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I also found the following statement in the article: *"When the industry starts an approval process for pesticides in the EU, it determines autonomously the pre-selection of the scientific studies on which it is to be based. This task was taken on by the "Glyphosate Task Force" (GTF), a conglomeration of glyphosate manufacturers headed by the seed company Monsanto."*
This is also incorrect.

What is true is that in accordance with the European plant protection product regulation, the manufacturers must submit all legally requested documentation to the responsible authorities, along with the studies published in the last ten years and their own risk assessment in the prescribed format so that an application for re-approval can be processed in the first place. In addition to this, any interested third parties can submit further studies. Furthermore, if certain hazard characteristics are relevant, the examining body must independently research and assess other published studies prior to reaching a decision. This was decided by the European Commission and European Parliament. Within the scope of the re-approval of the active substance glyphosate, more than 1,000 studies, documents and publications on health effects were reviewed and assessed in addition to the legally prescribed tests. On top of this, the BfR independently included comprehensive test results on co-formulants and residue trials in addition to the GTF data submitted. The commissioned authorities (Federal Office of Consumer Protection and Food Safety (BVL), Environmental Protection Agency (UBA), Julius Kühn Institute (JKI) and the BfR each conducted their own, independent risk assessments on the basis of these documents, as well as their own research and findings.

The EU procedure for active substance approval, for which the BVL is mainly responsible in Germany, can be determined through simple research conducted on the websites of the BfR or the German federal government.[2]

You use the following statement to support your contention that the authorities are industry-friendly: *"The German authorities are also regarded as industry-friendly in the authorisation process for chemical plant protection products. The related papers are commissioned and usually paid for by the plant protection industry itself. The so-called "grey studies" are not published and can often not be verified by independent researchers. The reason for the secrecy is that the studies are alleged to contain trade secrets."*

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[2] Popular misconceptions, opinions and questions in connection with the BfR risk assessment of glyphosate
BfR Communication No. 013/2016 of 19 May 2016
http://www.bfr.bund.de/cm/349/ popular-misconceptions-opinions-and-questions-in-connection-with-the-BfR-risk-assessment-of-glyphosate.pdf

Reply from the Federal Government of 11 May 2016
http://dipbt.bundestag.de/dip21/btd/18/084/1808408.pdf

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The legal procedure in Europe prescribes that the applicant has to conduct and pay for the toxicological studies for the active substance applied for. This complies with the general principle used in other authorisation processes, such as pharmaceuticals law where the manufacturer and/or distributor carries the responsibility for the safety of the products and must also provide proof of this. The studies have to be conducted in line with the principles of good laboratory practice (GLP) and OECD guidelines on the toxicological testing of chemicals, as well as EU test method regulation No. 440/2008. The guidelines stipulate among other things the number and species of the animals to be used and the control groups for each of the toxicological endpoints to be examined.

The sole criterion for the consideration of study results is the scientific quality and evidence of the studies. Possible interests of the commissioning party, politics or other interest groups cannot and may not play any role in the scientific assessment. The professional debate with sources presented by the applicants of industry (Glyphosate Task Force) is therefore a part of the legally prescribed assessment process.

What also applies to the BfR is that impartiality and independence are legally anchored in its statutes. The institute was founded in order to conduct risk assessments independently, scientifically and impartially and bolster consumer health protection. All of the civil servants and national government employees who work at the BfR must comply with the legal provisions of the German Civil Service. These include, for example, official regulations on impartiality, effectiveness, professional knowledge and the prevention of corruption as stipulated by German law and the implementation regulations of the Federal Ministry of the Interior (see Federal Civil Service Act, Art. Administrative Procedures Act and other regulations by way of example).To maintain its independence, no funding is solicited from trade and industry, nor does the BfR contribute financially to research projects of this kind.

It is mentioned in the article that the European Court of Justice ensured more transparency in the authorisation of glyphosate in November 2016. It would have been appropriate to also mention that the European Food Safety Authority (EFSA) published the data on glyphosate before the decision of the European Court of Justice was announced and that the BfR expressly welcomed this step in its communication of 30 October 2016 entitled “More transparency on glyphosate: BfR supports the release by EFSA of raw scientific data”.[3]

The following statement is also incorrect: *“In the BfR risk assessment, all independent examinations conducted by public institutions without any funding from industry were excluded from the evaluation; not a single one was regarded as a study.”*

[3] http://www.bfr.bund.de/cm/349/more-transparency-on-glyphosate-bfr-supports-the-release-by-efsa-of-raw-scientific-data.pdf

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This statement is completely unfounded. As an independent consumer health protection institution, the BfR has the remit of delivering a scientifically sound basis for the decisions reached by politicians. This means that all of the findings and available data in line with the latest level of available knowledge must also be included. This is precisely what we did in the case of the risk assessment of the plant protection product active substance by basing our scientific expertise on internationally recognised criteria, thus assuring the quality.

It goes without saying that in its report the BfR carefully reviewed and assessed all other relevant and available studies in addition to those of the applicants which were prescribed by law. This included all surveys irrespective of how they were funded. To perform the health assessment, the BfR conducted extensive research and reviewed and evaluated more than 1,000 studies, documents and publications. The assessment reports, including the related supplements made after evaluating the public and expert consultations and the BfR addendum on the evaluation of the IARC monograph, have been published on the EFSA website under www.efsa.europa.eu.[4]

The following statement is also not correct: *"Just to what extent evaluations of studies can deviate from one another became clear when the cancer agency of the World Health Organisation (WHO) classified glyphosate as "probably carcinogenic to humans". The general public as well as the experts questioned the estimation of the risk assessment made in Germany because, unlike the BfR, the WHO uses publicly sponsored studies and insists on access to the raw data of the studies so that the results can be verified."*

From a journalistic point of view it would have been honest here to mention that the IARC (International Agency for Research on Cancer) – an agency supported by the WHO – only carried out a hazard assessment. The JMPR (Joint FAO/WHO Meeting on Pesticide Residues) – the WHO committee responsible for the evaluation of pesticides – made an updated risk assessment of glyphosate on behalf of the WHO. In doing so, the JMPR – just like the BfR (after a peer review process in coordination with the European member states and EFSA) and other non-European authorities all over the world – concluded that in line with the current state of science, no risk of cancer in humans is to be expected from the intake of glyphosate via food if used correctly and for its intended purpose. This can be read not only on our website but also on that of the WHO.[5]

[4] The documents can be accessed at:
http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin

[5] http://www.bfr.bund.de/cm/349/ popular-misconceptions-opinions-and-questions-in-connection-with-the-BfR-risk-assessment-of-glyphosate.pdf

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The information for the readers that no risk assessment authority anywhere in the world currently comes to the conclusion that glyphosate should be classified as "carcinogenic" would have been important. If you were right, all of the following institutions would be mistaken:

- The European Food Safety Authority (EFSA) and experts of the risk assessment authorities of the EU member states
- The American environmental authority EPA
- The Canadian Pest Management Regulatory Agency (PMRA)
- The Australian Pesticides and Veterinary Medicines Authority (APVMA)
- The Japanese Food Safety Commission The New Zealand EPA and the
- Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The IARC bases its results on considerably fewer sources because, according to its preamble, no unpublished studies are included in its assessment. For this reason, some of the comprehensive studies submitted by the applicants were not available to the IARC.

The classification of the IARC is also based on published studies funded by industry:

The estimation of the IARC that glyphosate is carcinogenic with "sufficient evidence in animals" is based on the publication of long-term studies on rodents. These studies were financed by industry. Their assessment in both the BfR report as well as that of the American EPA and JMPR, was that no carcinogenic risk is to be expected for humans as a result of glyphosate. Unlike the BfR, the IARC did not have the original industry studies and most importantly, the raw data they contained, which could only be accessed indirectly via another publication.

The following statement is equally confusing: *"A panel of experts for genetically modified foods and feeds has been established at the Federal Institute for Risk Assessment (BfR) in Berlin. Ten of the initially fourteen, now twelve, scientists also worked in industry. Although this deplorable state of affairs has been known since 2012, only four experts have left the panel. The legally prescribed disclosure of their activities in industry was incomplete as well because the experts did not list all of their jobs with biotechnology companies."*

The BfR committees advise the BfR independently and on an honorary basis in open specialised scientific issues. These commitees are expressly challenged to reflect the current state of science and technology critically on the work undertaken at the BfR and to identify possible future work areas of risk assessment. The BfR acknowledges the opinions of the BfR committees on individual sets of circumstances, but the BfR committees are not involved in the risk assessments themselves.[6]

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[6] See the rules of procedure of the BfR committees which are published in the internet (German only) at http://www.bfr.bund.de/cm/343/geschaeftsordnung-der-bfr-kommissionen.pdf

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The BfR handles possible conflicts of interest with transparency: potential conflicts of interest of BfR committee members must be recorded in writing. To this end, the experts sign a declaration, which is then published on the BfR website. Moreover, spoken inquiries about conflicts of interest with the topics dealt with in the BfR committees are made at the beginning of every meeting. If a conflict of interest exists, the BfR committee member in question is excluded from the consultations on the corresponding topic and a note to this effect is made in the protocol of the meeting. All BfR committee protocols can be accessed on the BfR website. BfR employees are expressly barred from voting in the BfR committees, which means that the advisory work of the BfR committees is completely separate from official assessment procedures.[7]

Fifteen committees made up of external experts currently advise the BfR. These committees assure the highest possible scientific expertise within the BfR. The committee members come from universities and other research institutions, national and regional authorities, trade and consumer associations, private laboratories and industry. For the appointment period 2014 to 2017, the advisory council on appointments nominated a total of 187 experts as BfR committee members. Overall, roughly 50% of the experts have a university and university clinic background, including poison centres and non-university research institutions like the Fraunhofer institutes, 34% come from authorities such as national research institutions and regional food control agencies, and a further 16% from companies and industrial associations.[8]

Of the twelve current members of the BfR committee for genetically modified foods and feeds, eleven members work in the civil service (e.g. in regional or national offices and universities) or are retired. The committee in question is distinguished by a high level of personnel continuity. Only four experts from the previous appointment period (2011 – 2013) – all of them full-time civil service employees – did not reapply for the current appointment period (2014 – 2017). The reason that these four members left the committee had absolutely nothing to do with any conflicts of interest or alleged false statements connected with their committee work.

I also had to read the following assertion in the article: *"How does this conflict of interest affect decisions? In the meantime, word has already reached the USA regarding just how pro-industry the expert panel at the BfR reaches its decisions, since the new method of genome editing (CRISPR/Cas9) has not even been classified as a form of genetic engineering."*

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[7] Frequently Asked Questions on Ensuring the Independence of the Federal Institute for Risk Assessment
http://www.bfr.bund.de/cm/349/frequently-asked-questions-om-ensuring-the-independence-of-the-federal-institute-for-risk-assessment.pdf

[8] BfR Committees
http://www.bfr.bund.de/en/the_bfr_committees-644.html

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As the responsible decision-making instance, the European Commission has not yet issued any legal classification of the new method of modifying a genome, but it has announced the publication of an interpretation aid to help with classification. This factual information is missing in the article.

The contention that a committee that, from a purely legal point of view, is not empowered to reach any decisions in Germany or the EU is supposed to have made a decision which has effects also in the USA is remarkable and not founded. The BfR as a scientific institution is barred by law from deciding on how genome editing is to be legally classified.

It goes without saying that your newspaper has to conduct critical journalistic research and ask questions. Scientific results can and should be a source of social discussion – even if it is controversial – in a pluralistic, democratic society. It should be possible, however, to make a clear distinction between a report based on facts and the personal opinion of an author.

I would not have expected such a biased reporting, made on the basis of questionable investigations, from a newspaper whose editorial statutes are committed to truthful reporting to a critical readership. Critique as defined by Kant also means that a person's own findings and assumptions should be critically examined and questioned as well.

I wish you a happy new year

Yours sincerely,

Andreas Hensel

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