

Supplementary remarks on the process of assessing the plant protection product active substance glyphosate, on the independence of the BfR and on legal data requirements in assessment procedures

BfR Communication No. 033/2017 of 16 November 2017

In the course of a media inquiry, the German Federal Institute for Risk Assessment was asked how it conducted the health assessment of the plant protection product active substance glyphosate and whether the Institute conducted its own toxicological examinations of glyphosate. It was also questioned whether the BfR possesses the necessary laboratory capacity to conduct its own toxicological tests. Another question concerned the internal measures for ensuring assessment work based purely on scientific criteria, without any influence from economic or political interests.

In the following paragraphs, the BfR outlines once again in all brevity the procedure and measures for ensuring independent assessment work with regard to the approval process for the active substance glyphosate.

Authorisation process for plant protection products: Separate toxicological studies by the assessment authorities are not stipulated by law

It was determined by law that in the authorisation and approval process for plant protection products and/or their active substances, the applicants must submit data and studies on prescribed toxicological endpoints, which are then to be verified by each responsible authority in the course of an assessment. The assessment authorities are also obliged to include all available, published studies on an issue in their assessment, in line with their scientific relevance. The procedure does not provide for independent experimental studies by the authorities involved in the approval and/or assessment process.

The BfR has both chemical-analytical laboratories, as well as labs for conducting microbial and molecular biological examinations and labs for toxicological examinations in which experimental work is done. As separate studies by the assessment authorities are not stipulated within the scope of approval and authorisation processes, the BfR did not conduct its own studies or award any studies to third parties within the framework of the legal data requirements which have to be fulfilled by the applicant.

Irrespective of the approval process, however, the BfR either participated in tests or had them conducted over and above the legally prescribed studies. These studies concern the possible effects of glyphosate on livestock, in particular dairy cattle. Accordingly, the BfR commissioned studies at the Veterinary University Hannover in order to examine the effects of a glyphosate-containing herbicide on the ruminal bacteria of cattle. The results were evaluated and published jointly with the contractor (Riede et al., 2016, J. Appl. Microbiol., 121(3), 644-656; doi: 10.1111/jam.13190). The BfR was also involved in studies conducted by the Friedrich Löffler Institute and TiHo Hannover on the intake and excretion of glyphosate by conventionally farmed dairy cattle (Von Soosten et al., 2016, J.Dairy Sci., 99, 1-7). The results of the studies were taken into account in the addendum on the effects of glyphosate on animal health, which has not been published yet.

Principles of the assessment procedure

In its background information No. 029/2015 of 14 September 2015, the BfR gives a detailed description of legal assessment procedures in the field of plant protection.

<http://www.bfr.bund.de/cm/343/legal-procedures-in-the-field-of-plant-protection.pdf>

The legal procedure stipulates that the assessment authorities involved in the process in the areas of health and the environment must use and pay due consideration to the studies submitted by the applicants, including unpublished raw data, when assessing the substance in question. Studies and publications are only used in the assessment after thorough examination and assessment by each responsible authority, in Germany the UBA, JKI, BVL or BfR. All of the available studies published on an issue must also be researched, assessed with regard to their relevance and submitted by the applicants.

The authorities must also conduct their own literature research, especially if there is a suspicion of carcinogenic, genotoxic, reproduction toxic or endocrine-damaging properties. These publications have to be taken into account in line with their scientific relevance and quality. To this end, the BfR has further developed and published the existing criteria on this (Kaltenhäuser et al., 2017, Regul. Toxicol Pharmacol., doi: 10.1016/j.yrtph.2017.06.010). One of the over-arching principles of the assessment procedure is that the drafts of all assessment reports by the rapporteur member states are subjected to a peer review under the auspices of EFSA and released for public consultation. Only after consideration of the comments made by the other member states, scientific community and general public is the revised report subjected to a final review by panels of experts at EFSA. The resulting concerted EFSA assessment then forms the basis of the decision-making process at the European Commission.

Independent assessment by the BfR in the glyphosate approval process is guaranteed by legal and official regulations

The criteria prescribed through the legal regulations issued by the federal government are decisive for BfR staff. Through their employment contracts or civil servant status, all BfR employees are obliged to comply with the applicable rules and regulations. All civil servants and employees subject to collective salary agreements at the BfR must comply with the legal provisions that apply to the civil service. These include official regulations on aspects such as impartiality, effectiveness, expertise and corruption prevention, as prescribed under German law, as well as the implementation regulations of the Federal Ministry of the Interior (see Federal Civil Servants Act, Art. 10 Administrative Procedure Act and other regulations by way of example).

For this reason, as a minimum requirement, every scientific assessment made by the BfR is subjected to quality assurance measures in line with the "four-eye principle". To assure quality, the work of the BfR and the methods used are reviewed and audited on all levels at regular intervals by external bodies, such as the Federal Audit Office, Federal Office for Agriculture and Food (BLE), TÜV Nord etc.

http://www.bfr.bund.de/en/press_information/2017/41/european_assessment_of_glyphosate_was_conducted_with_quality_assurance_and_independently-202097.html

BfR committees not involved in approval and authorisation processes

The BfR committee members work as experts for the Institute in an honorary capacity and are obliged to act independently in the interest of the public. The BfR committees have a purely advisory function here; they are not involved in the operative core activities of the Institute, such as the health assessment of individual active substances and products within the scope of authorisation or approval proceedings. The results of the committees' scientific

consultancy are non-binding for the decisions of the BfR; they have a purely recommendatory character.

The committee members are selected by an appointment panel made up of externally appointed, independent experts. Any possible conflicts of interest with the topics dealt with in the BfR committees must be recorded in writing. The members sign a declaration to this effect which is published in the internet. An oral inquiry about possible conflicts of interest with the topics dealt with by the committee is made at the beginning of every meeting, and the results recorded in the minutes. If conflicts of interest exist, the experts in question are excluded from the resolution process. For reasons of transparency, the minutes of the meetings at which the scientific opinions and resolutions of the committees were formulated are published on the BfR website.

Soundness of the work by the BfR in the assessment of glyphosate is confirmed by the federal government and EU authorities

The BfR emphatically denies the accusations that it “did not work in the correct scientific manner” when assessing the health risks of glyphosate (plagiarism accusations). The assessment was conducted in accordance with the criteria prescribed in the legal EU procedure for the re-approval of the active substances contained in plant protection products. The Renewal Assessment Report (RAR) and subsequently prepared addenda do not constitute a report intended for publication by the author, the BfR, but rather a written document for use in a (European) administrative process. The benchmark is therefore the standards that apply in administrative matters, which differ from those used for scientific publications, doctoral theses and the like. In Europe and world-wide, it is customary and recognised – not only with plant protection products – that after making a critical review, assessment authorities also integrate relevant passages from submitted documents into their assessment reports. That is why the subdocuments of the assessment report also contain text passages of this kind from publicly accessible literature submitted by applicants as part of the legally required literature research. In addition to independent assessments, the overall evaluation made by the authorities always contain summaries of scientific findings from original studies and published literature too. These are thoroughly reviewed by the BfR experts with regard to their quality and relevance, as well as the experimental findings, with reference to the original literature and where necessary also with regards to any possible health issues. Just how customary this approach is is confirmed by the European Food Safety Authority (EFSA), who made the following statement in a press release on 22.09.2017: “If the RMS agrees with a particular summary or evaluation it may incorporate the text directly into the draft assessment report”. (https://www.efsa.europa.eu/sites/default/files/170922_glyphosate_statement.pdf)

In its reply to three inquiries from members of the Bundestag, the federal government also confirmed the proper course of action on the part of the BfR regarding the health assessment of glyphosate.

<http://dipbt.bundestag.de/doc/btd/17/103/1710373.pdf>

<http://dip21.bundestag.de/dip21/btd/17/142/1714291.pdf>

<http://dipbt.bundestag.de/doc/btd/18/136/1813696.pdf>

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