

Popular misconceptions, opinions and questions in connection with the BfR risk assessment of glyphosate

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Various press reports and citizens' inquiries connected with the risk assessment of glyphosate have induced the BfR to comment on some misconceptions frequently put forward in public.

- “The WHO first classified glyphosate as carcinogenic and has now changed its mind.”
- “There is no agreement among scientists. Therefore, politicians cannot make the decision.”
- “The reason for the difference between the BfR and IARC assessments is that the BfR relies on industry-sponsored studies.”
- “A significant increase of tumours caused by glyphosate has been reported in animal studies.”
- “Glyphosate has even been detected in breast milk.”
- “The glyphosate level in urine is way above the toxicological limit value.”
- “Glyphosate is even found in beer.”
- “Why don't you ban glyphosate?” or “Revoke the approval!”
- “The experts at BfR are not impartial.”
- “It was actually the agricultural industry (plant protection product manufacturers) that conducted BfR's risk assessment.”
- “Does the BfR advocate the renewed approval of glyphosate?”

“The WHO first classified glyphosate as carcinogenic and has now changed its mind.”

It was not the World Health Organisation (WHO) that classified glyphosate as probably carcinogenic but carried out by the International Agency for Research on Cancer (IARC), the specialized cancer agency of WHO. Just like BfR and other authorities all over the world, another WHO committee responsible for the assessment of pesticides, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), comes to the conclusion that in line with the current state of scientific knowledge, no carcinogenic risk or mutagenic changes are to be expected via food if glyphosate is used properly and for its intended purpose (http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/). BfR also assessed whether the active substance poses a risk to users, workers, bystanders or local residents when used properly. According to its own preamble, the IARC only performed a hazard identification, which can then be considered by national and international authorities in the course of their risk assessments (<http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>). This “Hazard identification” - in particular, the IARC classification of substances in terms of their carcinogenicity - is the first step of the “risk assessment” process. (<http://www.who.int/features/qa/87/en/>). Only when the hazard and the exposure are set in relation to each other can it be assessed whether a health risk exists for humans and how great it is. This means that IARC only completed the first step in the process of health risk assessment, which, where glyphosate is concerned, was completed by BfR, the European assessment authorities and JMPR by obtaining the possible health hazards of expected glyphosate contamination from agricultural applications.

“There is no agreement among scientists. Politicians cannot make a decision if it is not clear whether glyphosate is carcinogenic or not.”

The health risk assessment is currently undisputed. Just like BfR, the European Food Safety Authority (EFSA) and other authorities all over the world, the WHO committee responsible for the assessment of pesticides (JMPR) concludes that in line with the current state of scientific

knowledge, no carcinogenic risk is to be expected if glyphosate is used properly and for its intended purpose. There are different classifications for different aspects. The IARC and BfR have fundamentally different mandates, scientific criteria and approaches. The IARC does not conduct risk assessments, it analyses completely different hazards that are not intended to constitute a recommendation for any governments or authorities. The hazard-related classification relates to the potential property of an active substance to cause damage, e.g. “carcinogenic” (Category 1), such as alcohol, nicotine, processed meat (sausage) and asbestos, or “probably carcinogenic” (Category 2a), such as glyphosate or red meat. Classification of this kind does not take into consideration the actual intake quantity of the substance and thereby the likelihood of the damage actually occurring. Risk assessment, on the other hand, takes into account the quantity of a substance which humans actually ingest under realistic conditions. This means that IARC examines whether a substance is fundamentally capable of causing cancer, no matter under what conditions, whereas BfR additionally examines whether the substance actually does pose a risk if used properly.

Another reason for the differing estimations is that IARC only considers published studies in line with its statutes. This means that many studies are ignored, such as those prepared within the scope of the EU approval process, which are not published. Consequently, BfR was able to include many more recent studies in its report that IARC did not consider according to its preamble. Conversely, the BfR report assesses all of the studies to which IARC refers.

The fact that comparable authorities all over the world, including EFSA, the US Environmental Protection Agency (EPA) and JMPR, arrived at a comparable assessment also demonstrates that the risk assessment conducted by BfR is in line with the current state of scientific knowledge.

“The reason for the difference between the BfR and IARC assessments is that BfR relies on industry-sponsored studies.”

BfR is legally obliged to verify applicants’ documentation. It does not rely on this information, but rather conducts its own scientific research. In its report, it meticulously checked and assessed all of the applicants’ legally prescribed studies, as well as all other relevant and available studies. The IARC bases its results on far fewer sources because it does not include any unpublished studies in its assessment according to its preamble. That is why some of the comprehensive studies submitted by the applicants were not considered.

The IARC classification is also based on studies which were financed by trade and industry. The estimation by IARC that there is “sufficient evidence in animals” to show that glyphosate is carcinogenic is based on publications of long-term studies on rodents which were financed by trade and industry. They were evaluated by BfR as well as the EPA and JMPR, with the result that no carcinogenic risk for humans is to be expected from glyphosate. This means that the IARC assessment is also based on industry-sponsored studies. Unlike BfR, however, the originals of these studies were not available to IARC, which only had indirect access to them via another publication.

Contrary to IARC, all of the responsible authorities which had access to the originals of these studies came to the conclusion that classification of the hazard potential of glyphosate as “probably carcinogenic” cannot be made by scientific means and that no carcinogenic risk is to be expected from glyphosate if it is used properly and for its intended purpose.

“A significant increase of tumours caused by glyphosate has been reported in animal studies.”

The evaluation of the findings of animal experiments in toxicological studies requires special expertise. BfR not only evaluated the experimental studies conducted with rodents with regard to their statistical significance, but also using a weight of evidence approach, which includes the results of all methods of evaluating the results of animal experiments along with other findings. These include a reference to background contamination, historical controls, OECD recommendations on limit dosages and various statistical comparisons with reference to dose-response relationships, the consistency and reproducibility of effects, the plausibility with a mechanism of action and the consideration of uncertainty influences, as intended by the OECD, ECHA and EFSA guidelines for the testing of chemicals. In this way, BfR arrived at the conclusion that neither the studies on rats nor on mice give any indication of a carcinogenic or mutagenic risk of glyphosate.

The experts of the European member states as well as JMPR and the US EPA arrived at the conclusion that no biologically relevant increase in tumour incidence with relevance for humans was to be observed in any of the treated groups of animals in the eleven long-term studies on rats and mice that were considered. According to the interpretation of IARC, on the other hand, two of the studies are alleged to show statistically significant effects on non-malignant tumours in the pancreas. IARC also determined a positive trend in the number of renal tumours and haemangiosarcomas in two studies on male mice, but not for malignant lymphomas. Apart from the fact that the assessment authorities BfR, EFSA and JMPR included a larger number of studies in the overall evaluation, they considered the increases of individual tumours observed exclusively with very high doses as not relevant to humans with regard to expected intake, as they could also be attributable to the influence of a general toxicity among the animals. The OECD also deliberately recommended a limit dose of 1000 mg/kg bw for reasons of animal welfare.

BfR, EFSA and the European member states also evaluate whether the active substance in a pesticide can pose a health risk to users, workers, bystanders or local residents if used properly. Only when a corresponding risk cannot be scientifically expected can an active substance be given further approval by the Commission. This means that the European assessment of the active substance goes even further than the assessment of the WHO/FAO committee JMPR.

“Glyphosate has even been detected in breast milk.”

Some media reported in 2015 that glyphosate had been measured in 16 breast milk samples. This test was conducted on the basis of a method (ELISA) which is not suited for measuring glyphosate in breast milk. Details of how this test was conducted have not been published. The glyphosate concentrations in the samples are alleged to have been measured between 0.21 and 0.43 nanograms (ng), or 0.0000000021 and 0.0000000043 grams (g), per millilitre (ml), which means they were roughly 200 times lower than the quantitation limit of 75 ng per ml that the manufacturer of the ELISA test stated to be reliable. In addition to this, the alleged findings in breast milk were not confirmed by an independent analysis method. That is why BfR expressed scientific doubt about the reliability of these results and commissioned its own study in order to obtain substantiated and verified results.

BfR commissioned research laboratories renowned throughout Europe with the development of two independent analysis methods with high sensitivity, which were then used to examine 114 breast milk samples from Lower Saxony and Bavaria. This study confirmed that no residues of the active substance glyphosate which is used in plant protection products can be detected in breast milk.

http://www.bfr.bund.de/en/press_information/2016/08/bfr_study_confirms_no_glyphosate_detectable_in_breast_milk-196578.html

One important reason for the BfR study was that concerned mothers had made inquiries at BfR for information about the alleged risk of glyphosate residues in breast milk. Breast milk continues to be the most natural and therefore best food for babies.

“The glyphosate level in urine is way above the toxicological limit value.”

Residues of plant protection products are permitted in food up to a certain maximum limit. They can be ingested and degraded up to this guide value without endangering health. The residue level permits no conclusions about the toxicity of an active substance. If urine contains residues of undesired substances, this is an indication that the substance was excreted. Only when it is known how much of the substance remains in the body can it be established whether this is a quantity which could damage health.

If the urine values published to date are calculated back to the daily intake quantity of glyphosate, it is shown that a person calculated to have a glyphosate level of roughly 4 ng, or 0.0000000004 g, per ml of urine has ingested less than a hundredth of the tolerable daily intake of 0.5 milligrams (mg) per kilogram (kg) of body weight. These data therefore confirm the estimated intake quantities that BfR calculated in the residue assessment within the scope of the EU active substance examination, and they give no cause for concern according to the latest level of available scientific knowledge.

http://www.bfr.bund.de/en/press_information/2016/11/glyphosate_in_the_urine_even_for_children_the_detected_values_are_within_the_expected_range_without_any_adverse_health_effects-197173.html

Comparisons with the guide value for drinking water are confusing and are often quoted in the discussion about the health risks posed by substances, even though they are usually unscientific. This means that the guide value for plant protection product residues in drinking water is not derived from health aspects, but rather is a politically established precautionary value that applies to all plant protection products. A health hazard does not therefore automatically exist if the guide value for drinking water has been exceeded. The decisive factor is to establish whether the ingested (and not the excreted) quantity of a substance exceeds the scientifically calculated guide value. What applies here in principle is that a great many substances, both desired and undesired, are excreted in urine. This in turn means that glyphosate levels in urine are to be expected from a scientific point of view and are not unusual.

“Glyphosate is even found in beer.”

According to media reports, 14 beer varieties were tested for glyphosate residues at the beginning of 2016. If the (highest) values published in the media are used as the basis for calculation, a person would have to drink 1,000 litres of beer every day to reach the toxicological limit value. Residues of the active substances used in plant protection products are permitted in legally acceptable concentrations and are to be expected. Constantly improving, ever more sensitive analysis methods result in the ability to detect substances virtually everywhere in the meantime, even in concentrations as low as one femtogram (0.000000000000001 g). The existence of a substance or residues thereof is therefore no indication of a health risk.

The actual health risk was actually overlooked in the report about glyphosate in beer, namely the intake of alcohol. Alcohol is carcinogenic and reprotoxic in much smaller quantities.

“Why don’t you ban glyphosate?” or “Revoke the approval!”

BfR does not have the legal remit to decide whether the active substances in plant protection products are to be approved or not. This also applies to glyphosate. One of the reasons for this is the legally established separation of risk assessment and risk management that applies in Germany and the European Union (EU). BfR is tasked with the scientific risk assessment of substances. Decisions on approval, authorisation or banning, on the other hand, fall into the category of risk management and are therefore made by competent authorities, such as the Federal Office of Consumer Protection and Food Safety (BVL) or Federal Ministry of Food and Agriculture (BMEL), as well as the national government and European Commission.

“The experts at BfR are not impartial.”

The impartiality and independence of BfR are anchored in law. BfR was founded on 1 November 2002 under the direction of Green Party minister Renate Künast in order to conduct independent, scientific, non-partisan risk assessments, thus enhancing consumer health protection. All of the civil servants and salaried employees who work at BfR must comply with the legal provisions of the German Civil Service. These include, for example, official regulations on impartiality, effectiveness, professional knowledge and corruption prevention, as prescribed by German law and the implementing regulations of the Federal Ministry of the Interior (see Federal Civil Service Act, Art. 10 Administrative Law Act and other regulations). The main task of BfR is to take up a position on the possible health risks of foods, products and chemicals, thus advising the federal ministries in their political decisions. For reasons of independence, no funding is raised from trade and industry and BfR has no financial involvement in research projects of this kind.

“It was actually the agricultural industry (plant protection product manufacturers) that conducted BfR’s risk assessment.”

According to the European plant protection product regulation, in order to even have a re-approval application reviewed, the manufacturers must first submit all legally required documentation and studies to the responsible authority along with the applicant’s own risk assessment. This was decided by the German *Bundestag* and European Parliament. The authorising authority in Germany is the Federal Office of Consumer Protection and Food Safety (BVL). The commissioned authorities then prepare an independent risk assessment on the basis of this documentation and their own research and knowledge. The scientific assessment of risks with regard to human health is a sovereign task which is performed exclusively at BfR by the institute’s own staff, i.e. civil servants and salaried employees subject to wage and salary negotiations, without any external advice or assistance from the likes of representatives of trade and industry, associations or businesses. BfR does not receive funding of any kind or form from private institutions, nor does it enter into any cooperation projects with them.

BfR is independent and may not accept any financial or other benefits from private institutions such as enterprises, associations or private individuals in connection with its professional activities. BfR is not tied to any directives issued by the BMEL either where risk assessment and communication are concerned. Consequently, BfR is both politically and economically independent and does not represent any political or business interests. Risks are assessed solely on the basis of scientific criteria.

“Does BfR advocate the renewed approval of glyphosate?”

BfR is strictly neutral where this is concerned and argues neither for nor against the renewed approval of glyphosate or any other pesticide active substances. BfR does not make any political or management decisions in accordance with its legal remit.

The health risk assessment of glyphosate conducted by BfR showed that, as far as can be established by the current state of scientific knowledge, no carcinogenic risk is to be expected if the substance is used properly and for its intended purpose. This assessment was confirmed by experts in the other EU member states and the European Food Safety Authority (EFSA), as well as the WHO/FAO committee Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Irrespective of a science-based health assessment, the EU Commission can decide against the approval of a substance for other reasons, such as ethical or political reservations, but this does not affect the impartiality and professional objectivity of the BfR risk assessment.