Epidemiological studies on glyphosate: No new findings for the European risk assessment

European assessment authorities, IARC and BfR unanimously derive the classification “limited evidence for carcinogenicity in humans” from epidemiological studies

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The assessment of epidemiological studies on the health effects of glyphosate is currently being discussed in the media. In this context, BfR evaluated a so-called expert opinion on epidemiological studies prepared by non-government organisations and concludes that no new findings are being reported for the joint European assessment of the active substance glyphosate.

The accusations brought forth in the so-called expert opinion of scientific deception by the assessment authorities are completely unfounded and their content provides no new contribution to the scientific discourse. They were not made available in the public consultation or in a peer-reviewed publication.

The BfR assessment report (RAR) that is criticised in the so-called expert report was extensively commented upon and evaluated by the general public, science, politics, trade and industry and NGOs within the scope of the consultations of the European Food Safety Authority (EFSA) on glyphosate. The report was confirmed and its contents were adopted by the experts of the member states, thus making it a European risk assessment and no longer a BfR or EFSA risk assessment. The assessment report is available to the EU Commission and member states for the purpose of reaching a decision on the re-authorisation of the active substance glyphosate.

Incidentally, the result of the RAR complies with the specialised assessment of the epidemiological studies conducted by the International Agency for Research on Cancer (IARC), who also classified the indications for the carcinogenicity of glyphosate in humans on the basis of the epidemiological studies as merely limited (“limited evidence in humans”).

It is alleged in this so-called expert opinion that BfR employees attempted to assess epidemiological methods with a method recommended for the assessment of animal experiments, with the result that the studies were dismissed as “scientific rubbish” (not reliable). In actuality, BfR used the method developed for toxicological studies with the goal of transparently appraising the applicability of the results of individual studies for the health assessment of the active substance glyphosate and specifying limitations of the studies for the renewal of approval of the active substance by the EU. This approach had the result that a study was assessed as “not reliable” if, for example, it was only usable from a regulatory point of view to a very limited extent, if at all, because certain information was not sufficiently or not at all reported in the publication. The regulatory assessment “not reliable” should therefore be understood as “not reliable for the approval of the active substance glyphosate”. The appraisal “not reliable”, on the other hand, cannot be interpreted as it was in the so-called expert opinion to imply that the studies in question were regarded as scientifically flawed.

It is also claimed in the so-called expert opinion that studies were dismissed in the RAR as “not reliable” because allegedly relevant data (e.g. smoking behaviour) was not collected. What is correct here is that although questions were indeed asked about numerous relevant lifestyle factors, their influence on the result was not always reported in a transparent and comprehensible manner. Information that was left out of the publications cannot form the

basis of scientific assessment. This was already discussed in detail at a hearing in the German *Bundestag* before the Committee on Food and Agriculture: https://www.bundestag.de/blob/414880/beef8a72a4655c5ac707f412e934b81d/protokoll_40_sitzung_neu-data.pdf

The procedure for the renewal of approval of the active substance glyphosate follows the same procedural rules and principles that apply to all other active pesticide substances in a European community procedure under the auspices of the EU Commission. In the current EU active substance approval procedure for glyphosate, the Federal Institute for Risk Assessment (BfR) scientifically verified and evaluated all studies available up to the editorial deadline of the various assessment reports with the greatest care and attention. This includes all of the epidemiological studies quoted by the International Agency for Research on Cancer (IARC) in its monograph. The results of these epidemiological studies are classified as being of little relevance for the assessment of the active substance by BfR, as well as by the assessment authorities of the EU member states and other countries throughout the world.

As a basic principle, BfR recommends that scientific studies be discussed within the scope of consultation or on a scientific level, regardless of how controversial these discussions may turn out to be. In this context, the scientific publication process is an integral part of science. Theses and comments on studies can only be added to the scientific discourse if they are published and the corresponding conclusions outlined as transparently as possible.

More information on the BfR website on the subject “Glyphosate”:
http://www.bfr.bund.de/de/a-z_index/glyphosat-126638.html