

EU active ingredient test for glyphosate: current situation and outlook

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Glyphosate is one of the most common active ingredients in plant protection products used to prevent unwanted plant growth in plant cultivation and to accelerate the maturation process of crops (desiccation). Glyphosate inhibits a plant enzyme which is essential for the biosynthesis of certain amino acids. This enzyme is not found in animals or humans. The approval procedure for glyphosate as an active ingredient is currently being revised at the European level. Germany is hereby the Rapporteur Member State (RMS). For the purpose of reassessing the health implications of this active substance, the Federal Institute for Risk Assessment (BfR) has, in its capacity as the competent federal institute, examined and evaluated more than 150 new and original toxicological studies conducted in accordance with the OECD guidelines and Good Laboratory Practice (GLP) and over 900 new studies published in scientific journals, which included the analysis of numerous documents not previously considered. This investigation did not provide any indications that glyphosate has carcinogenic, reprotoxic or teratogenic effects on test animals, nor did the documents give any cause for substantially changing the health-based limit values. The first draft of the Renewal Assessment Report (RAR) was issued at the end of 2013 and subsequently submitted to the European Food Safety Authority (EFSA) by the Federal Office of Consumer Protection and Food Safety (BVL). Adopting a peer review system, public consultation with experts and stakeholders was completed under the guidance of EFSA in 2014.

Changes and extensions to the report on the assessment of the health implications of glyphosate by the BfR following public consultation

Taking into account the submitted comments of the member states, the EFSA, the Glyphosate Task Force (GTF) and the public consultation, the Renewal Assessment Report (RAR) was revised. Moreover, all GTF documents additionally requested by the BfR, as well as articles not yet considered, or newly published in scientific journals were all incorporated. This revised version of the RAR was sent to the BVL in December 2014.

For the revised version, a total of about 350 comments and references were individually checked, assessed and, when required, taken into account in the revision of the RAR.

The revised version incorporated a significantly increased number of biographical references, and included more and longer sections on the detection of glyphosate in human urine. It also contained more information on its effects on agricultural production animals. However, the amendments also covered the areas of carcinogenicity and mutagenicity. Even though a higher absorption rate through the skin is now assumed for the representative formula, i.e. a plant protection product containing glyphosate as its active ingredient, this has not changed the basic assessment of the substance.

Further activities of the Federal Institute for Risk Assessment (BfR)

As the BfR communicated to the EFSA as early as July 2014, the evaluation of the public consultation led to the conclusion that some questions require general clarification at the European level, since they are of major importance and from the viewpoint of substance effects are not directly connected to glyphosate.

The BfR therefore recommended to the European Commission to hold a general discussion with experts specialising in health-based risk assessment from the member states, universities, the industry, NGOs and politicians, in order to consult with them on these points and to adumbrate possible solutions for an improved assessment of the health risks posed

by plant protection products. As part of these solutions, possible new toxicological assessment procedures and reinforced integration of alternative method validation must be taken into account and ways must be found to better characterise active ingredient / co-formulant combinations.

The BfR continues, within the framework of separate projects, to investigate certain aspects of health assessment. A publication on the detection of glyphosate in human urine has already been completed [1]. A further publication on the effects of a glyphosate-containing herbicide on the bacteria population in an artificial rumen model and on parameters of the rumen metabolism are currently underway, as is a comparative study of poisoning incidents in Germany and in a Brazilian federal state.

[1] Solecki et al (2015), A critical review of glyphosate findings in human urine samples and comparison with the exposure of operators and consumers. Journal für Verbraucherschutz und Lebensmittelsicherheit. DOI 10.1007/s00003-014-0927-3
<http://link.springer.com/article/10.1007/s00003-014-0927-3/fulltext.html>