

Animal welfare provisions and good laboratory practice: German federal states ("Länder") investigate possible breaches by an animal experiment laboratory

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According to information from the competent Harburg administrative district authority, the operating licence of the laboratory test facility "LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG" in Mienenbüttel was withdrawn. The facility is suspected of having breached animal welfare provisions. These allegations are now being investigated by the authorities. In addition, it is being reported in the media that the laboratory in question manipulated study results and has therefore infringed the principles of "Good Laboratory Practice" (GLP).

The German federal states ("Länder") monitor compliance with animal welfare provisions and GLP provisions via their authorities in charge.

GLP monitoring in Germany is legally based on the National Chemicals Act (Chemikaliengesetz) and the General Administrative Provisions on Good Laboratory Practice (Allgemeine Verwaltungsvorschrift zur Guten Laborpraxis). Monitoring is carried out by the competent authorities at federal state level. The German Federal Institute for Risk Assessment (BfR) is not involved in GLP inspections.

The purpose of GLP is to safeguard the quality and comparability of non-clinical health studies and environmental safety studies for substances, mixtures and solutions for scientific assessment.

The GLP Federal Bureau set up within the BfR is responsible for coordinating and harmonising GLP-related issues at national and international level. The BfR is not responsible for GLP monitoring private laboratories in Germany. The functions of the GLP Federal Bureau are listed on the following website:

https://www.bfr.bund.de/en/statutory_tasks_of_the_glp_federal_bureau-1490.html.

Allegations regarding possible breaches of GLP are reviewed by the respective regional authority of the German federal state ("Land"). Non-conformities and falsifications cannot generally be ruled out entirely. However, due to the provisions on GLP compliance these are only possible with high effort and criminal energy.

Some of the studies conducted by LPT have been submitted by the glyphosate applicant to the scientific authorities for re-approval. 24 LPT studies have been reviewed along with more than 900 other studies and publications in a European assessment process. The focus of the LPT studies was primarily on investigations into acute effects and tests on skin and eye irritation. The health effects investigated by LPT as well as by others resulted in the classification of the active ingredient as an "eye irritant", for example. Public debate has focussed on whether or not glyphosate causes cancer. LPT has not conducted any tests on the long-term toxicity of glyphosate that are the essential basis for assessing carcinogenesis.

Three out of the 24 studies dealt with mutagenicity. In these three studies, no indications of mutagenicity were identified. These studies were assessed jointly with many other studies from different sources. The evaluation of all studies in the European process resulted in glyphosate not being classified as mutagenic.

Glyphosate has already been assessed at EU level with the involvement of all Member States and the public consultation.

The BfR currently sees no reason to question the overall assessment of glyphosate due to the 24 LPT studies. Nevertheless The BfR will continue to monitor the investigations and, if necessary, take these into account in its decisions.

Further information on the topic of glyphosate is available from the BfR website:

https://www.bfr.bund.de/en/a-z_index/glyphosate-193962.html

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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