

BfR reported fully on all the available information regarding the assessment of the carcinogenicity of glyphosate

Cited 2-year study in mice shows no toxicologically significant risk of carcinogenicity in humans

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In response to recent inquiries regarding a 2-year study on mice, the Federal Institute for Risk Assessment (BfR) would like to point out that, within the context of EU active substance approval, all relevant studies on the carcinogenicity of the active substance were reviewed, assessed and included in the public presentation. At a public symposium at the ICC in Berlin on 20 January 2014 attended by representatives of politics and science, for example, the BfR referred to the high-dose effects observed in the study cited by the FAKT television programme. This study found an increased incidence of lymphomas in a mouse strain with a high level of spontaneous incidence at a dose of 1,460 mg per kg body weight per day (2,920 times the accepted daily intake amount) after 18 months. This increase was not observed in other studies with even higher concentrations in some cases. The German government presented the assessment of the BfR and discussed it in detail in the Committee for Food and Agriculture as well as in a full session of the German Bundestag parliament. The International Agency for Cancer Research (IARC) had access to the detailed assessment report of the BfR within the framework of the public consultation carried out by the European Food Safety Authority (EFSA).

Like all other active substances used in plant protection agents, glyphosate is periodically re-assessed with regard to its risks to health and the environment as well as in terms of its efficacy within the context of the EU active substance evaluation. Germany is the rapporteur state for the communal evaluation and assessment of glyphosate. In the re-assessment procedure, the BfR was commissioned to assess the health risk of the active substance and one formulation. For the purpose of health assessment, the BfR reviewed and evaluated over 1,000 studies, documents and publications.

In the overall data package for the renewed active substance approval for glyphosate, the BfR also had access to a total of eleven animal studies investigating potential carcinogenic effects. These studies are incorporated in the BfR's assessment report. This report was published in April 2014 as part of the public consultation carried out by EFSA; it was therefore available to interested members of the public and hence also to the IARC.

The studies listed in the assessment report also included a 2-year study of mice in which different amounts of glyphosate had been mixed with the feed. The glyphosate dose administered in this study was higher than the limit dose recommended by the OECD (Organisation for European Cooperation and Development). Although an increase in malignant lymphomas was observed at a very high dose, this effect was classified as toxicologically not relevant. Findings of this kind are not unusual from the point of view of international experts. The study was reviewed and assessed in line with the scientific guidelines agreed within the European Union, as is also regularly the case for all other toxicological studies. The findings of this study assessment were commented on by the other member states as well as during the public consultation.

The BfR described the cited study both in this preliminary assessment and in the revised assessment report sent to EFSA. In the cited study, the incidence of malignant lymphomas in the animals in the highest dose group (10,000 mg glyphosate per kilogram of feed, equivalent to roughly 1,460 mg/kg body weight per day) was elevated compared to the control group. Based on current knowledge in the field, the overall data basis does not supply any sufficient evidence for the classification of glyphosate as carcinogenic.

The following aspects need to be taken into account with regard to the assessment:

1. The finding was only observed at an extremely high dose above the limit dose of 1,000 mg/kg body weight per day for long-term and carcinogenicity studies recommended by the OECD.
2. The finding was observed in a mouse strain exhibiting a high spontaneous incidence of malignant lymphomas; thus, malignant lymphomas also occurred in the untreated 20% of male and 36% of female control animals.
3. Four further valid carcinogenicity studies using mice observed no significant increase in malignant lymphomas; thus, the finding was not reproducible.

The German government presented and discussed the assessment of the BfR in the Committee for Food and Agriculture of the German Bundestag parliament. In addition, it also forwarded the 18-page preliminary assessment of the BfR on the cancer risk from glyphosate to the Committee for Food and Agriculture. During the committee meeting, the German government informed the committee members about the contents of the preliminary assessment and answered questions from the parliamentary groups of all the political parties.