EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and Biocides

Brussels,
SANTE/E4/MW/gl

Dear Petitioner,

Subject: **Open letter: Review of unwanted effects to human health conditions by the German Federal Institute for Risk Assessment (BfR)**

Thank you for the abovementioned letter which outlines concerns with regards to the evaluation process for the consideration of renewal of approval of glyphosate and about the impact of glyphosate on human health.

I would like to first of all assure you that the renewal assessment for glyphosate was conducted in line with the rules laid down in the legislative framework for pesticides; Regulation (EC) No 1107/2009[1].

The burden of proof for the safety of an active substance ('pesticide') for use in plant protection products lies with the company that seeks to place the product on the market. To that end, it has to follow strict guidelines which are laid down in EU legislation and guidance documents produced by the European Food Safety Authority (EFSA). This is the same system used, for example, with medicines. Specific studies, required by legislation are therefore paid for by industry, but are conducted under strict scientific conditions in certified laboratories, ensuring that regulatory bodies have full access to relevant information without bias from the study sponsors. The role of Member States and EFSA is to critically review the studies and information submitted by industry to determine whether the strict approval criteria detailed in the legislation are satisfied.

As part of the renewal evaluation of glyphosate, a comprehensive and transparent assessment of all available data and information was carried out by the Rapporteur Member State (RMS), Germany, and peer reviewed by all other EU Member States and the European Food Safety Authority (EFSA). A public consultation was carried out on the assessment by the RMS which provided a platform for citizens and other stakeholders

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, p. 1–50

to voice their concerns. Furthermore, the European Commission requested EFSA to take into account the assessment of the International Agency for Research on Cancer (IARC)[2] during the peer review, to ensure that all relevant information was available for its Conclusion[3]. The peer review process also included detailed expert discussion on the carcinogenic potential of glyphosate, and took epidemiological data into account.

The Commission has carefully considered the findings presented in the EFSA Conclusion and has discussed these with Member States, taking into consideration the legal framework laid down in Regulation (EC) No 1107/2009. Taking into account all legitimate factors and in light of the current scientific knowledge, it is the Commission's view that it is appropriate to renew the approval of glyphosate. A formal legal act laying down the conditions for continued approval will be presented to the Standing Committee on Plants, Animals, Food and Feed for its opinion.

I understand that there are concerns and fears from citizens about glyphosate and exposure to it from food and other sources; this is taken very seriously by the Commission. However, I would like to reassure you that the European Union has the most stringent regulatory system for pesticides in the world, ensuring the highest safety standards for human and animal health and the environment, underpinned by sound science.

Yours sincerely,

Michael Flüh
Head of Unit

2 http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf

3 EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302