

## EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation Pesticides and Biocides

Brussels, SANTE/E4/MW/np

Dear Petitioner,

Subject: Petition: "Glyphosat von Monsanto: Pestizid-Vergiftung beenden"

Commissioner Andriukaitis asked me to respond to your petition on his behalf.

Firstly, let me assure you that your concerns are taken very seriously. I understand that there is fear and concern about glyphosate and exposure to it from food and other sources, and also misunderstanding about how the process for considering approval of active substances in the European Union operates.

I would like to reassure you from the outset that the EU 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. The relevant procedures, which also apply in the case of glyphosate, are described on the European Commission's website: <a href="http://ec.europa.eu/food/plant/pesticides/index\_en.htm">http://ec.europa.eu/food/plant/pesticides/index\_en.htm</a>.

The Commission has and will continue to remove active substances from the market for which it could not be demonstrated that the strict approval criteria enshrined in the legislation are satisfied. It is never the case that substances are allowed to be placed on the market and used when there are serious safety concerns for human health.

In the case of the evaluation of a possible renewal of the approval of glyphosate, a comprehensive and transparent assessment of all available data and information was carried out by the Rapporteur Member State (RMS) Germany. That assessment was then 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 to voice their concerns. Furthermore, the Commission requested EFSA to take into account the assessment of the International Agency for Research on Cancer (IARC)<sup>2</sup> during the peer review, to ensure that all relevant information was available for its Conclusion<sup>3</sup>. The peer review process

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

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

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

also included detailed expert discussion on the carcinogenic potential of glyphosate, and took epidemiological data into account. All assessments and peer review documentation have been made available via the EFSA website<sup>4</sup>.

With regards to the assessment of carcinogenicity, the outcome of the EU peer review, as presented in the EFSA Conclusion, is that glyphosate is "unlikely to pose a carcinogenic hazard to humans". It should also be noted that recently the Joint UN Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues (JMPR) risk assessment on glyphosate, published on Monday 16 May 2016, concluded in its summary report that "glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet"<sup>5</sup>.

The Commission services have carefully considered the findings presented in the EFSA Conclusion and have discussed these with Member States, taking into consideration the legal framework laid down in Regulation (EC) No 1107/2009, which concerns the placing on the market of plant protection products.

Based on extensive discussions with Member States, the Commission adopted on 29 June 2016 a Commission Implementing Regulation<sup>6</sup> to extend the expiry date of glyphosate until 31 December 2017 to enable the European Chemicals Agency (ECHA) to deliver its opinion on the classification of glyphosate (in particular related to carcinogenicity). Once an opinion of the Risk Assessment Committee of ECHA is available, the Commission will consider this in the context of the further discussions on glyphosate.

In parallel to the extension of the approval, the Commission has already presented to Member States a series of recommendations on the use of glyphosate. Discussions with the Member States have started at expert level, and the Commission will work to have them adopted as soon as possible.

Yours sincerely,

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Michael Flüh Head of Unit

http://www.efsa.europa.eu/en/press/news/151119a

Summary Report from the May 2016 Joint FAO/WHO Meeting on Pesticide Residues (JMPR), 16 May 2016 <a href="http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1">http://www.who.int/foodsafety/jmprsummary2016.pdf?ua=1</a>

Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate. OJ L 173, 30.6.2016, p. 52–54