

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation Pesticides and Biocides

Brussels, SANTE/E4/MW/df

Dear Petitioner,

Subject: Petition: "Re-authorisation of glysophat for another 18 months"

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: http://ec.europa.eu/food/plant/pesticides/index_en.htm.

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. Substances are not 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)² during the peer review, to ensure that all relevant information was available for its Conclusion³. The peer review process also included detailed expert discussion on the carcinogenic potential of glyphosate, and

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

took epidemiological data into account. All assessments and peer review documentation have been made available via the EFSA website⁴.

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 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 its summary report concluding that "glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet"⁵.

The Commission carefully considered the findings presented in the EFSA Conclusion and discussed these in depth with Member States, taking into consideration the legal framework laid down in Regulation (EC) No 1107/2009. The Commission services made a proposal to renew the approval of glyphosate to Member States, but there was no qualified majority in support of this proposal.

Subsequently, based on extensive discussions with Member States, the Commission made a proposal to extend the expiry date of glyphosate until 31 December 2017 (at the latest) to enable the European Chemicals Agency (ECHA) to deliver its opinion on the hazard properties of glyphosate. This measure has now been adopted⁶, although without the support of a qualified majority of Member States.

On 11th July 2016, a qualified majority of Member States in the Standing Committee on Plants, Animals, Food and Feed voted in favour of a proposal by the Commission to amend the approval conditions of glyphosate. These conditions include a ban of the coformulant POE-tallowamine from glyphosate-based products and obligations to reinforce scrutiny of pre-harvest uses of glyphosate as well as to minimise the use in specific areas (public parks and playgrounds).

These were not easy decisions for the Commission but I consider it essential that the Commission adopts sound science-based decisions, to ensure a high level of protection for human health and the environment.

Yours sincerely,

Michael Flüh Head of Unit

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

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

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.