



13th October 2021

Stella Kyriakides
Health Commissioner for Health and Food Safety

Dear Commissioner Kyriakides,

We, the 41 undersigned civil society organizations including several of the organisers of [the European Citizens' Initiative #stopglyphosate](#) are writing to you to express our concerns about the current renewal assessment procedure of the pesticide active substance glyphosate and in particular about the credibility of the studies that have been provided by industry to justify its authorisation renewal in Europe. Independent peer-reviewed scientific literature has associated exposure to glyphosate-based herbicides with certain types of cancer in humans¹ as well as to adverse effects on early life development and hormonal systems². Therefore, in the context of the European Green Deal to protect citizens' health and EU's Beat Cancer Action Plan to prevent cancer, the toxicity reassessment of glyphosate should take place under close scrutiny.

¹ Weisenburger DD. A Review and Update with Perspective of Evidence that the Herbicide Glyphosate (Roundup) is a Cause of Non-Hodgkin Lymphoma. Clin Lymphoma Myeloma Leuk. 2021 Sep;21(9):621-630. doi: 10.1016/j.clml.2021.04.009..

² Manservigi et al. The Ramazzini Institute 13-week pilot study glyphosate-based herbicides administered at human-equivalent dose to Sprague Dawley rats: effects on development and endocrine system. Environ Health. 2019 Mar 12;18(1):15. doi: 10.1186/s12940-019-0453-y

With this letter we call on you to:

- provide guarantees that the current assessment procedure is based on updated independent scientific evidence, takes into consideration the toxicity of the active substance glyphosate as well as of glyphosate-based products, and remains free from vested interests;
- support the ongoing [Global Glyphosate Study](#) undertaken by the Ramazzini institute, which is the most comprehensive toxicity study ever done on a pesticide.

Background

Back in 2015, the International Agency of Research on Cancer (IARC) [classified glyphosate as “probably carcinogenic to humans”](#). According to EU law (EC 1107/2009), this class of chemicals are not permitted to be used as active substances in pesticide products.

In the meantime, however, the German Health Authority (BfR), followed by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), concluded that the substance did not pose any other health hazard or risk to humans, be it for carcinogenicity, mutagenicity, reproductive toxicity, or endocrine disruption. The contradiction in the carcinogenicity assessment between EU authorities and IARC, together with the demand of over one million citizens to ban glyphosate because of health concerns, resulted in Member States agreeing to renew the glyphosate license only for five years instead of the initially proposed 15-years period.

Ahead of the expiry of the current license (expected on 15th December 2022), the re-assessment of glyphosate is underway. To our great concern, the four Member States leading the assessment (France, the Netherlands, Sweden, Hungary) and forming the Assessment Group on Glyphosate released similar preliminary conclusions, according to which glyphosate meets the approval criteria set in the EU pesticide Regulation (EC 1107/2009). The draft assessment reports have now been delivered to ECHA and EFSA in order to complete the hazard and risk assessments, respectively.

Questions regarding the credibility of the EU assessment procedure, primarily based on industry studies

The differing conclusions between the assessments of IARC and of the EU authorities have sparked unprecedented scientific and political debates in the history of pesticide renewal discussions. It is important to highlight that IARC’s evaluations are consistently based on the systematic assembly and review of all publicly available and relevant studies. They are carried out by independent experts, who are free from vested interests due to a strict policy on [ethics, independence](#) and [scientific misconduct](#). IARC’s evaluations are, in fact, the gold standard when it comes to carcinogenicity assessment. In contrast, the EU assessment is based predominantly on unpublished and non-peer-reviewed studies that are commissioned and provided by the companies which are selling the pesticide products.

[Several independent scientists](#) have criticized the EU glyphosate assessment on carcinogenicity, pointing out important flaws and alerting that the EU conclusion is not supported by all the available scientific evidence. Two different reviews of the industry-funded carcinogenicity studies, obtained following the publication of the European and US assessment reports and the release of certain full laboratory reports through a [court decision](#), exposed important scientific misconducts: the companies

failed to report cancer incidents that had been observed in experimental animals³ or had misinterpreted the data, and that such failure was later overlooked by the authorities.^{3,4}

A [recent independent scientific analysis](#) reinforces the doubts on the credibility of the industry studies that were used during the previous EU glyphosate authorisation process for the assessment of genotoxicity (the mechanism that underlines cancer development). Out of the 53 industry genotoxicity studies examined, 34 were identified as “not reliable”, 17 as “partly reliable” and only 2 studies were found “reliable” from a methodological point of view.

According to a [first screening](#) of the glyphosate renewal dossier submitted by the applicants in 2019, all 38 genotoxicity studies on the active substance that were previously accepted as valid or supplementary have been re-submitted for the purpose of the current evaluation. This unfortunately indicates that the proposed genotoxicity assessment of glyphosate is not based on studies that can be considered reliable.

Keeping this background in mind, we call on you to reassure the over one million citizens who signed the ECI that the current renewal process of glyphosate is based on updated scientific evidence, free from vested interests, and allows for third-party scrutiny.

Lack of chronic toxicity studies on glyphosate product formulations

In the context of the IARC glyphosate assessment, the IARC Working Group evaluated studies of ‘pure’ glyphosate as well as studies of glyphosate-based formulations. Experts reached the same hazard conclusion: the evidence for genotoxicity was ‘*strong*’ for glyphosate and ‘*strong*’ for glyphosate formulations.

Glyphosate formulations, contrary to the active substance, correspond to the products that operators and bystanders are using and/or are exposed to. Therefore, their toxicity is of high relevance for the protection of humans as well as the environment. Formulations however, are approved individually at the Member State level through a less rigorous procedure than the active substance assessment and they are not tested by industry applicants for long-term toxicity. Therefore, whole products and co-formulants that are toxic may enter the market. This contradicts the provisions of the Regulation (EC) 1107/2009 that aims to ensure that active substances, residues and products cause no harm to human and animal health, and the environment.

In a recent ruling, the Court of Justice of the European Union clarified that Regulation 1107/2009 does not exempt industry applicants from submitting tests of long-term carcinogenicity and toxicity relating to formulated plant protection products as sold and used ([Case C-616/17](#)). However, Member States do not require such tests, even when evidence on long-term toxicity cannot be ruled out.

In the context of the current evaluation, we call on you to ensure that the EU assessment examines and takes into account the long-term toxicity of both pure glyphosate and glyphosate-based products. This step would also be in line with the EU’s Beat Cancer Action Plan which aims to prevent cancer before it starts.

The Ramazzini Institute’s Global Glyphosate Study - an opportunity to resolve remaining doubts in the context of the recently introduced Transparency Regulation

³ Portier, C.J. A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies. Environ Health 19, 18 (2020). <https://doi.org/10.1186/s12940-020-00574-1>

⁴ Clausing P, Robinson C, Burtscher-Schaden H. Pesticides and public health: an analysis of the regulatory approach to assessing the carcinogenicity of glyphosate in the European Union. J Epidemiol Community Health. 2018;72(8):668-672. doi:10.1136/jech-2017-209776

The [Global Glyphosate Study](#) of the Ramazzini Institute is the first of a kind long-term animal toxicity study, which is currently being performed in one of the most world-renowned animal facilities. The study is compliant with Good Laboratory Practices and combines four international study protocols in one study. It is designed to look at the following:

- (1) Real life exposures, at low environmental levels, to glyphosate and to two glyphosate-based products;
- (2) The following health endpoints: toxicity, carcinogenicity, prenatal developmental toxicity, neurotoxicity, multi-generation effects, endocrine disruption, and effects on the microbiome.

In the context of past controversies regarding the evaluation of glyphosate and the important questions that currently remain, the provisions of the recently introduced Transparency Regulation (EU) 2019/1381 could help safeguard the scientific excellency and the independence of the evaluation that is underway.

The Transparency Regulation not only promises to increase the independence of studies that are used for risk assessment, but it also provides that in '*circumstances of serious controversies or conflicting results*', the Commission may request EFSA to commission scientific studies with the objective of verifying evidence used in its risk assessment process. **The glyphosate evaluation is illustrative of such circumstances and the Ramazzini Glyphosate Study is an independent study that could be supported to cater for them.**

Therefore, we call on the European Commission to financially support this study, as an urgent priority and ensure that all the available results are duly reported and taken into account in the EU evaluation of glyphosate.

We thank you for considering this letter, which illustrates existing and continuously growing public concerns on the toxicity of glyphosate and glyphosate-based products. We look forward to your response and would welcome the opportunity to discuss these important questions in a meeting at your earliest convenience.

Yours sincerely,

Genon K. Jensen

Executive Director

Health and Environment Alliance (HEAL)

On the behalf of:

European/International NGOs

Avaaz

Corporate Europe Observatory

European Federation of Food Agriculture and Tourism Trade Unions (EFFAT)

Foodwatch International

Greenpeace

Health and Environment Alliance (HEAL)

Health and Environment Justice Support (HEJSupport)

International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations (IUF)

Justice Pesticides

Pesticide Action Network (PAN) Europe

Slow Food Europe

Sumofus

WECF International

WeMove Europe

National NGOs

Austria

Foodwatch Austria

Global 2000

Belgium

Vereniging voor Ecologisch Leven en Tuinieren (Velt)

Croatia

Eco Hvar

France

Alerte des Médecins sur Les Pesticides (A.M.L.P)

Foodwatch France

Génération Futures

Réseau Environnement Santé

WECF France

Germany

Aurelia Stiftung

Bündnis für eine enkeltaugliche Landwirtschaft e.V.

Foodwatch Germany

Pesticide Action Network (PAN) Germany

Slow Food Deutschland

Umweltinstitut München e.V.

WECF Germany

Italy

International Society of Doctors for Environment (ISDE) Italy

Slow Food Italia

The Netherlands

Foodwatch Netherlands

Pesticide Action Network (PAN) Netherlands

Tegengif

WECF Netherlands

Spain

Confederación de Ecologistas en Acción

FODESAM (Fondo para la Defensa de la Salud Ambiental)

Hogar sin Toxicos (Vivo Sano Foundation)

United Kingdom

GMWatch

Earth Thrive

The [Health and Environment Alliance \(HEAL\)](#) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health. HEAL EU transparency register number: 00723343929-96