

Brussels, 24/03/2017

## Dear President Juncker,

The EU approval of the world's most used herbicide active substance, glyphosate, will expire 6 months from the date the Commission receives the opinion of the Committee for Risk Assessment of the European Chemicals Agency or on 31 December 2017, whichever the earliest is.

Last week, on March 15th, the European Chemical Agency communicated that its "Committee for Risk Assessment (RAC) agrees to maintain the current harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. RAC concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction."

This assessment follows the one made by the European Food Safety Authority in a report issued on 12 November 2015 that concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans. The report was nevertheless proposing a new safety measure to tighten the control of glyphosate residues in food.

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Meanwhile in the United States, a litigation has been brought by people who claim to have developed non-Hodgkin's lymphoma as a result of exposure to glyphosate.

It was echoed in press reports that last March 13th, a U.S. District Judge ruled that documents obtained by plaintiffs could be unsealed. The court documents include internal emails from Monsanto, a member company of the Glyphosate Task Force (GTF), which is a "consortium of companies joining resources and efforts in order to renew the European glyphosate registration with a joint submission". Later on those documents were called "Monsanto Papers" by Le Monde.

According to an article in Le Monde on March 18th, the information revealed through the emails is that already in 1999 Monsanto knew about genotoxic effects of glyphosate. James Parry, a renowned genotoxicologist Monsanto had worked with, concluded that glyphosate

had potential clastogenic effects in vitro and suggested to conduct more specific studies on the potential mutagenic effects of glyphosate. The revealed emails show Monsanto regretted to have worked with Parry and intended not to pursue the suggested studies. James Parry died in 2010.

Furthermore, <u>internal emails from the summer 2012</u>, and referred to in an <u>article from Huffington Post</u>, suggest that Monsanto had ghost-written research that was later attributed to academics. The reasoning appearing in the emails at that time was that "it unfortunately turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility". A so-called "need to re-group and redesign the approach to the manuscript" was identified.

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As Members of the European Parliament, we are deeply concerned to see that one of the published studies used in the *Renewal Assessment Report of glyphosate: Risk assessment provided by the rapporteur Member State Germany and co-rapporteur Member State Slovakia* (see Final addendum uploaded on EFSA's website on 19/11/2015) was the *Review of genotoxicity studies of Glyphosate and Glyphosate-based formulations*, Critical Reviews of Toxicology, 2013; 43(4): 283–315.ASB2014-9587.

This study was co-authored by Kier and Kirkland. Both of them are cited in the "Monsanto Papers": L. Kier is a <u>former Monsanto expert and now toxicology consultant</u>. The released emails show concern about the level of credibility he would bring: "given his geography and industry alignment, other highly credible genotoxicologists coauthors from European were sought. David Kirkland was the first choice".

An internal email dated from July 12, 2012 refers to the signature of a contract between Monsanto and David Kirkland: "this will enable him to coauthor the genotoxicity review paper with Larry Kier, as well as engaging him on any other projects which may come up...it may be necessary to have an EU based expert in genotoxicity on hand if issues arise during the regulatory review".

The authors concluded that "an overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and its formulations were not genotoxic in these core assays." On page 57 of the Final addendum, you can read that "Taking a weight of evidence approach, it may be concluded that there is no in vivo genotoxicity and mutagenicity potential of glyphosate or its formulations to be expected under normal exposure scenarios, i.e., below toxic dose levels."

In the final EFSA *Peer Review Report on Glyphosate* uploaded on EFSA's website on 23/11/2015 you can read on page 1392 that during the meeting of 27 February 2015, notably based on this study, the Pesticides peer review meeting "confirmed that the active substance glyphosate is devoid of genotoxic potential", despite comments raised by PAN-Europe, PAN-UK and Agrar Koordination that "genotoxic effects on the contrary are already long known and available to the reviewers".

Contrary to EFSA and ECHA, IARC concluded in March 2015 that glyphosate is probably carcinogenic to humans. On page 45 of IARC's monograph on glyphosate, one can see that IARC did not include the study in question by Kier and Kirkland in their evaluation: "The Working Group determined that the information in the supplement to Kier & Kirkland (2013) did not meet the criteria for data inclusion as laid out in the Preamble to the IARC Monographs, being neither "reports that have been published or accepted for publication in the openly available scientific literature" nor "data from governmental reports that are publicly available" (IARC, 2006). The review article and supplement were not considered further in the evaluation."

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In light of all the above elements and of the non-selective properties<sup>1</sup> of glyphosate, for the sake of credibility of EU institutions and agencies, we urge you as President of the European Commission:

1/ with regard to glyphosate, to **take any urgency measure** necessary to guarantee the immediate protection of public health - including occupational health - and of the environment, based on Regulation (EC) No 1107/2009;

2/ to recommend ECHA and EFSA to critically revise the validity of the GTF studies used, and take all the necessary steps to investigate the impact of the 2013 Review of genotoxicity studies of Glyphosate and Glyphosate-based formulations led by Kier and Kirkland on both EFSA and ECHA conclusions on the carcinogenicity of glyphosate;

3/ not to propose any new approval of glyphosate in the EU as long as point 2/ has not been clarified and before all the restrictions on its use as adopted in the resolution of the European Parliament in April 2016 are put in place;

4/ to **urgently grant financial and technical support to the agricultural sector** for a rapid transition towards glyphosate-free agriculture;

5/ to propose a revision of the pesticides legislation that would ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published peer-reviewed and independent studies, which are commissioned by competent public authorities instead of the pesticide industry;

6/ to set up a black list of the companies which use lies as a common policy and, similarly to article 5.3 of the UN Framework Convention on tobacco control (FCTC), to forbid undisclosed direct contacts of European Commission and Agencies officials with any lobbyist working with or for Monsanto.

<sup>&</sup>lt;sup>1</sup> A recalled in the European Parliament resolution of April 2016, glyphosate is a non-selective herbicide that kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem; as such, glyphosate fails to comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009

7/ to fully investigate whether Monsanto has deliberately falsified studies on the safety of glyphosate and, should it be established, take appropriate legal action against the corporation.

## Yours sincerely,

Philippe Lamberts, Co-President of the Greens/EFA group, Guillaume Balas MEP (S&D), Jose Inacio Faria MEP (EPP), Stefan Eck MEP (GUE/NGL), Piernicola Pedicini MEP (EFDD), Bart Staes MEP (Greens/EFA), José Bové MEP (Greens/EFA), Martin Häusling MEP (Greens/EFA), Benedek Jávor MEP (Greens/EFA), Michèle Rivasi MEP (Greens/EFA), Maria Heubuch MEP (Greens/EFA), Molly Scott Cato MEP (Greens/EFA), Claude Turmes MEP (Greens/EFA), Ernest Urtasun MEP (Greens/EFA), Florent Marcellesi MEP (Greens/EFA), Marco Affronte MEP (Greens/EFA), Pavel Poc MEP (S&D), Karin Kadenbach MEP (S&D), Maria Noichl MEP (S&D), Nessa Childers MEP (S&D), Gilles Pargneaux MEP (S&D), Marc Tarabella MEP (S&D), Nicola Caputo MEP (S&D), Christel Schaldemose MEP (S&D), Eric Andrieu MEP (S&D), Isabelle Thomas MEP (S&D), Edouard Martin MEP (S&D), Younous Omarjee MEP (GUE/NGL), Eleonora Evi MEP (EFDD), Marco Zullo MEP (EFDD).