



29 October 2015

Mr. Vytenis Andriukaitis
 European Commissioner for Health and Food Safety
Vytenis.Andriukaitis@ec.europa.eu

By email only

Glyphosate – Need for a robust and credible scientific assessment of carcinogenicity

Dear Commissioner Andriukaitis,

We are writing to articulate our serious concerns regarding the authorisation renewal assessment report on glyphosate that was produced under the aegis of German authorities and forms the basis for the ongoing peer review by the European Food Safety Authority (EFSA).

The WHO's International Agency for the Research on Cancer (IARC) has classified glyphosate as a "*probable carcinogen*".¹ This classification was based on "*limited evidence*" in humans and "*sufficient evidence*" in experimental animals as well as "*strong evidence*" that glyphosate exhibits two characteristics associated with carcinogens, namely genotoxicity and the ability to induce oxidative stress.²

The health risk assessment prepared by the German Federal Institute for Risk Assessment (BfR), on the other hand, stated that glyphosate was "*unlikely to pose a carcinogenic risk to humans*" and that there was "*no evidence of a genotoxic potential*".³

In seeking to identify the reasons behind the contradictory findings, a number of independent scientists have reviewed draft versions of the German renewal assessment report from December 2013⁴ and March 2015.⁵ They have established that significant flaws exist in the German assessment report, notably:

- The report fails to assess a wide range of published peer-reviewed literature studies, which were evaluated by the IARC.
- Where the report does assess published peer-reviewed studies, it dismisses many of them as not relevant, while the IARC judged the same studies to be relevant.
- The report downplays positive findings of carcinogenicity in published reports of regulatory animal studies, yet no adequate justification is given for dismissing these findings.
- The report fails to assess oxidative stress as a potential mechanism of causing cancer.
- The report's conclusions are largely based on unpublished regulatory studies provided by the chemical companies producing glyphosate. This is particularly worrying given the contradictory interpretations that have been made of the published evidence.

Over the summer, the BfR re-evaluated some of the evidence in light of the IARC review. In an addendum to the final renewal assessment report from August 2015 it now acknowledges the positive findings of carcinogenicity in several animal studies. It also admits that they initially "*relied on the statistical evaluation provided with the study reports*" submitted by the glyphosate producers, instead of carrying out their own evaluation of the data. However, its overall conclusion remains that "*there is no carcinogenic risk related to the intended herbicidal uses*".

¹ A similar EU classification as carcinogen category 1B "presumed to have carcinogenic potential for humans" would render glyphosate ineligible for re-approval in the EU.

² IARC, Monograph on Glyphosate, July 2015, <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf>

³ Renewal Assessment Report, December 2013. For a more recent statement, see http://www.bfr.bund.de/en/the_bfr_has_finalised_its_draft_report_for_the_re_evaluation_of_glyphosate-188632.html

⁴ Professors Rusyn, Portier and Greiser, Stellungnahmen zur öffentlichen Anhörung http://www.bundestag.de/bundestag/ausschuesse18/a10/anhoerungen/anhoerung_glyphosat_28_09_2015/386986

⁵ Clausing, Peter, The Glyphosate Renewal Assessment Report. An Analysis of Gaps and Deficiencies, September 2015, http://blog.campact.de/wp-content/uploads/2015/10/Glyphosat-Studie_Campact_PAN_korrigiert.pdf

The BfR has stated that “(t)he fact that different bodies assess issues differently ... is part and parcel of the risk assessment process”.⁶ This clouds the fact that the BfR has not performed its assessment with the same level of resources and to the same rigorous standards followed by the IARC. The IARC Working Group comprised 17 world-class independent experts, assisted by the IARC secretariat. The experts took a year to review the evidential base for a single potential health effect of glyphosate, namely carcinogenicity, working to established review protocols in an open and transparent process.

In addition, an expert task force, which was set up to illuminate similar differences between two WHO bodies, the IARC and the Joint Meeting on Pesticide Residues (JMPR), concluded that the JMPR, which assessed glyphosate as non-carcinogenic, had to redo its work, properly taking into account published peer-reviewed literature.⁷

We are deeply concerned that, within the limited time available, the ongoing EFSA peer review cannot make up for the serious shortcomings of the German renewal assessment report.

Therefore, in the interest of protecting European citizens' health, we are asking you to

- Task the European Chemicals Agency (ECHA) to carry out a thorough analysis of carcinogenicity and other relevant 'endpoints' as part of its forthcoming assessment of harmonised classification and labelling (CLH), in addition to those endpoints proposed by Germany;
- Ensure that the EFSA peer review of the German renewal assessment report is scientifically robust and credible, incorporating the outcome of the harmonised classification and labelling (CLH);
- Immediately impose a ban on the use of glyphosate where it results in the greatest public and worker exposure, either directly or through residues in food.⁸

In the absence of scientific consensus that glyphosate is not harmful, the Commission has a responsibility to protect the public and workers from exposure to harm. As long as different scientific bodies come to different conclusions about the carcinogenic nature of glyphosate it is the obligation of the European Commission to invoke the precautionary principle. More than 1.4 million citizens are calling on the EU's decision makers to apply that principle to glyphosate use.⁹

Finally, we insist that, as a matter of principle, agencies such as EFSA should not issue scientific opinions, which form the basis of regulatory action, based on unpublished scientific evidence. All their work should be transparent and carried out by independent researchers without conflicts of interest.

In view of the public interest in this matter we will make this letter available on our websites.

⁶ BfR, Does glyphosate cause cancer?, March 2015, <http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf>

⁷ WHO Core Assessment Group on Pesticides, Expert Task Force, September 2015, Main findings and recommendations, http://www.who.int/foodsafety/areas_work/chemical-risks/main_findings_and_recommendations.pdf?ua=1

⁸ This demand has already been made by the Alliance for Cancer Prevention, Friends of the Earth Europe, Greenpeace, Health and Environment Alliance and Pesticide Action Network in a letter of 7 April 2015.

⁹ Avaaz petition, https://secure.avaaz.org/en/monsanto_dont_silence_science_loc_eu/

Yours sincerely,

Jorgo Riss,
Director,
Greenpeace European Unit

Génon K. Jensen
Executive Director,
Health & Environment Alliance
(HEAL)

F. Veillerette
President,
PAN Europe

Also on behalf of:

Avaaz
Bee Life
CHEM Trust
Center for International Environmental Law (CIEL)
ClientEarth
Corporate Europe Observatory (CEO)
European Network of Scientists for Social and Environmental Responsibility (ENSSER)
Foodwatch
Friends of the Earth Europe
Health Care Without Harm (HCWH) Europe
International Federation of Organic Agriculture Movements (IFOAM) EU
International Network on Children's Health, Environment and Safety (INCHES)
International Society of Doctors for the Environment (ISDE)
Women in Europe for a Common Future (WECF)

ÄrztInnen für eine gesunde Umwelt (AeGU), Austria
Agrar Koordination, Germany
Alliance for Cancer Prevention (ACP), UK
Bond Beter Leefmilieu (BBL), Belgium
Breast Cancer UK (BCUK), UK
BUND, Germany
Campact, Germany
Cancer Prevention and Education Society (CPES), UK
Danish Ecological Council, Denmark
Danish Society for Nature Conservation, Denmark
Ecologistas en Accion, Spain
Fondation Sciences Citoyennes, France
Fundación Vivo Sano, Spain
Générations Futures, France
GMB Trade Union, UK
GMWatch, UK
Fédération Inter-Environnement Wallonie (IEW), Belgium
Leefmilieu, Netherlands

Nature & Progres, Belgium
Pestizid Aktions-Netzwerk (PAN Germany)
Pesticide Action Network Italia (PAN Italy)
Pesticide Action Network UK (PAN UK)
Polish Ecological Club (PKE), Poland
Quercus, Portugal
Réseau Environnement Santé (RES), France
RISK Consultancy, UK
Test Biotech, Germany
Velt, Belgium
Wemos Foundation, Netherland

Armenian Women for Health and Healthy Environment (AWHHE), Armenia