Brussels, 11 April 2018

Glyphosate: an emblematic failure of the EU pesticides regime

Dear Member of the European Parliament's PEST Committee,

The glyphosate controversy and the eventual decision to re-approve the chemical for another five years has exposed some fundamental failures of the EU's pesticide approval system. It revealed the staggering influence of chemical companies on EU scientific assessments and a complete disregard for the concerns of independent scientists, the European Parliament and the general public.

The glyphosate assessment turned the EU's precautionary approach on its head: despite strong evidence of harm, the EU labelled glyphosate as 'safe' and imposed no EU-wide restrictions, let alone a ban. The EU, which claims to have a pesticides authorisation procedure that is *"the strictest in the world"*[1], has left its citizens exposed to a weedkiller that the WHO's International Agency for Research on Cancer (IARC) says is a probable cause of cancer.

The glyphosate case is emblematic. The European Food Safety Authority (EFSA) said that the chemical's assessment was "consistent" with general practice.[2] This raises serious concerns that similar failures could be repeated in other, less scrutinised assessments.

We therefore welcome the creation by the European Parliament of a special committee on the EU's pesticides approval process. We believe the Committee can play an important role in documenting and remedying the shortcomings of the EU pesticides regime.

Monsanto's undue influence

The so-called *Monsanto Papers*, a large swath of the company's internal documents released under US Court procedures, exposed some of Monsanto's methods to influence regulators on its "flagship" glyphosate products. We question whether the EU has done enough to counter these efforts and to deliver a truly "independent, objective and transparent assessment", as required by EU pesticides law.[3]

- **EFSA relied mainly on unpublished industry studies** for its assessment of whether or not glyphosate can cause cancer.[4] Worse, it relied on the glyphosate industry's own interpretation of the data contained in these studies and thereby failed to identify a large number of tumour increases linked to the exposure to glyphosate.[5] Its evaluation of industry studies has come under heavy criticism.[6]

- By contrast, **EFSA ignored most independent scientific studies on glyphosate**. Again, this is because it espoused the glyphosate industry's own evaluation of these critical studies. Large sections of the report underlying the EFSA conclusion were copied directly from Monsanto's application for the re-approval of glyphosate. Just as

Monsanto discarded most of the studies into glyphosate's long-term health impacts as "irrelevant" and "unreliable", the EU did so too.[7]

- In addition, **EFSA drew on industry-sponsored review papers** to guide its assessment of glyphosate. These papers "served to summarise or substantiate the industry position on glyphosate", EFSA said.[8] Some of them may have been "ghost-written" by Monsanto's in-house scientists themselves.[9] The EU report on glyphosate not only references these industry-sponsored review papers, it also endorses the views provided in them.[10]

The European Commission failed to investigate these issues. For example, the Commission accepted EFSA's assurances that Monsanto's evaluation of independent studies had been duly reviewed and amended.[11] This is despite the fact that EFSA was unable to demonstrate any independent review of the sections copy-pasted from Monsanto. At the Monsanto Papers hearing of 11 October 2017 at the European Parliament, EFSA instead pointed to unrelated sections of the report.[12]

At no point did the European Commission ask EFSA to reconsider any part of its glyphosate assessment. This is in stark contrast with its approach to EFSA's assessment of *diquat*, another herbicide. On 19 February 2018, the Commission asked EFSA to review a critical part of its evaluation, based on concerns raised by the chemical's manufacturer, Syngenta.[13]

Environmental impact ignored

EFSA concluded that all but one of the uses of glyphosate posed a "risk to wild non target terrestrial vertebrates". It identified a high long-term risk to mammals for some of the main uses and said that it was unable to assess long-term risks to small herbivorous mammals (e.g. voles) and insectivorous birds, due to insufficient data. In addition, the European chemicals agency (ECHA) classified glyphosate as "toxic to aquatic life with long lasting effects". However, the Commission claimed that the "EU assessment did not provide any evidence that indicates ecosystem degradation caused by glyphosate".[14]

Passing the buck to EU Member States

While rejecting any action to restrict glyphosate at the EU level, the Commission instead asked EU Member States to consider national-level measures. For example, EU Member States could mitigate "the risk to terrestrial vertebrates and non-target terrestrial plants" and "the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates".[15]

The Commission also asked EU Member States to carefully consider potential health impacts of glyphosate-based products, such as genotoxicity (i.e. damage to DNA).[16] EFSA highlighted the need to "address" long-term impacts such as the ability to cause cancer, damage DNA and interfere with reproduction.[17]

By asking EU Member States to deal with risks identified at the EU level, the Commission has simply discharged its responsibility for ensuring effective protection of human health, animal health and the environment.

The re-approval glyphosate has seriously damaged trust in the EU and its ability to protect Europeans from harm. With your help, we hope that the PEST Committee can rebuild this trust by investigating the failures of the EU pesticides regime and by making practicable recommendations for improvement.

Yours sincerely,

Mika Leandro, WeMove.EU

Also on behalf of:

Greenpeace European Unit
Générations Futures
Health and Environment Alliance (HEAL)
GLOBAL2000 - Friends of the Earth Austria
Campact
Corporate Europe Observatory (CEO)
Pesticide Action Network Europe
Pesticide Action Network Germany
Pesticide Action Network Italy
SumOfUs
Danmarks Naturfredningsforening
Skiftet
Umweltinstitut München e.V.
Ecologistas en Acción
The Danish Ecological Council
Fundación Alborada
GMWatch
Nature & Progrès Belgique
Slow Food
The International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations (IUF)
European Federation of Food, Agriculture and Tourism Trade Unions (EFFAT)
GENUK e.V.

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[1] Glyphosate: Commission proposes the way forward, statement by Commissioner Andriukaitis on 1 June 2016
[2] EFSA statement addressing stakeholder concerns related to the EU assessment of glyphosate and the "Monsanto papers", 23 May 2017
[3] REGULATION (EC) No 1107/2009, Article 11

[4] EFSA explains the carcinogenicity assessment of glyphosate, 12 November 2015
[5] Letter by Prof Portier to Commission President Juncker, 28 May 2017; Response by EFSA and ECHA saying they had "not specifically documented" these findings, 5 July 2017
[6] Portier, C et al, 2016, Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA); Clausing, P et al, 2018, Pesticides and public health: an analysis of the regulatory approach to assessing the carcinogenicity of glyphosate in the European Union
[7] Monsanto's view of independent science copied into EU evaluations, Greenpeace press release, 15 September 2017; Weber, S, 2017, Expert opinion on adherence to the rules of good scientific practice in the subsections B.6.4.8, B.6.5.3 and B.6.6.12 of the "Final addendum to the Renewal Assessment Report. Risk assessment […] for the active substance GLYPHOSATE […]"
[8] EFSA Statement regarding the EU assessment of glyphosate and the so-called "Monsanto papers", 8 June 2017
[9] Monsanto Weed Killer Roundup Faces New Doubts on Safety in Unsealed Documents, New York Times, 14 March 2017
[10] The Addendum to the glyphosate report openly supports the "principles for the evaluation of published studies" outlined in an industry-sponsored publication (Kier & Kirkland 2013). Other industry reviews considered in the EU glyphosate assessment include Williams, Kroes & Munro (2000), Heydens, Healy, Hotz, Kier, Martens, Wilson & Farmer (2008), Williams, Watson & DeSesso (2012).
[11] EFSA statement addressing allegations on the renewal assessment report for glyphosate, 22 September 2017
[12] Presentation by José Tarazona to the ENVI and AGRI Committee hearing , 11 October 2017. The examples are from the Renewal Assessment Report, Volume 3, Section B.6.5.1 (slides 11 and 12) and Volume 3, Section B.6.6.1 (slides 15 and 16). The sections that were copied and pasted from the industry application were Volume 3, Sections B.6.4.8, B.6.5.3 and B.6.6.12.
[13] Commission request for an updated peer review concerning the non-dietary exposure risk assessment of diquat, 19 February 2018
[14] Commission Communication on the European Citizens Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", 12 December 2017
[15] Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017
[16] Final Review report for the active substance glyphosate, 9 November 2017
[17] EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, 12 November 2015, p. 11: "EFSA noted that other endpoints should be clarified, such as long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of formulations."