11 April 2016

Dr Vytenis Andriukaitis
European Commissioner for Health and Food Safety
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Cc: Dr Bernhard Url, EFSA Executive Director
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By email only

Glyphosate – Your request for publication of confidential industry studies

Dear Commissioner Andriukaitis,

We refer to your letter of 4 April 2016 to Richard P. Garnett of Monsanto Europe, Chairman of the Glyphosate Task Force, an industry consortium pressing for continued approval of glyphosate. In this letter you requested the full publication of confidential industry studies on the potential carcinogenicity of glyphosate, an active ingredient in many widely used herbicides.[i]

The European Food Safety Authority (EFSA) examined 14 animal carcinogenicity studies, among other evidence, and concluded that glyphosate is not carcinogenic.[ii] The International Agency for Research on Cancer (IARC) evaluated eight of these studies, which were publicly available. It classified glyphosate in March 2015 as "*probably carcinogenic to humans*".[iii]

EFSA has underlined the fact that it "*assessed more evidence including additional key studies that were not considered by IARC*".[iv] It stressed that "*unpublished studies that were the core basis of the peer review evaluation were not available to the IARC experts*".[v] This has raised expectations that the additional studies not seen by IARC must contain compelling evidence proving that glyphosate is not a carcinogen.[vi]

We therefore appreciate your attempt to bring greater clarity to the glyphosate controversy by allowing independent scrutiny of these studies. However, your letter also raises some serious questions.

Why are you asking for an exceptional release of the studies, instead of publication based on existing EU transparency rules?

In December 2015, Corporate Europe Observatory requested that EFSA, under EU transparency rules, disclose five mouse carcinogenicity studies that were evaluated as part of the glyphosate risk assessment. The first response by EFSA was negative, arguing that disclosure of the studies would *"put at risk the commercial interests and intellectual property rights of their owners"* and that *"no overriding public interest on disclosure applied to this request"*.[vii] A final response is still pending despite the fact that legal deadlines have expired.

It is our strong view that the public should have access to all scientific evidence submitted by pesticide producers, based on EU transparency rules, namely Regulation 1049/2001 on public access to European institution documents, and Regulation 1367/2006 on the application of the Aarhus Convention. This cannot be a one-off favour granted to an exceptional request by a single politician. When it comes to public health and environmental protection, transparency must be the rule.

The recent opinion of Advocate General Juliane Kokott in case C-442/14 at the European Court of Justice confirms this. [viii] Laboratory studies on the impact of pesticides fall under the definition of 'information on emissions into the environment' of the Aarhus Convention. This means that there is an overriding public interest that requires disclosure, and the grounds for refusal must be interpreted in a restrictive way.

Why are you only requesting the release of certain studies when it is clearly in the public interest that all evidence assessed by EFSA must be published?

The animal carcinogenicity studies evaluated by EFSA are described in the Addendum to the Renewal Assessment Report issued by the German Federal Institute for Risk Assessment (BfR).[ix] (This Addendum was published after IARC finalised its evaluation of glyphosate.) According to the information available, several of the studies not seen by IARC show a significant increase in different types of tumours due to glyphosate exposure, supporting IARC's carcinogen classification.[x] More detail would certainly be helpful to fully evaluate these results.

EFSA dismissed the worrying findings of these studies partly because the incidence of tumours was, reportedly, within the range of control data from other animal studies (so-called *"historical controls"*). However, only one set of historical control data is referenced in the EFSA report, and the use of that data is inconsistent with established OECD and ECHA guidelines.[ix]

It is essential that all the data on which EFSA based its conclusion are on the table for independent evaluation, including the historical control data used.

As a matter of principle, EFSA scientific opinions, which form the basis of regulatory action, should be based on published scientific evidence. Restrictive access under the conditions of a *"physical reading room"*[xi] fails to fulfil this requirement. It has no place in an open scientific process.

The aim must be that all EFSA assessments, not only on glyphosate, can be reproduced by any expert who wishes to do so. Only in this way will EFSA be able to restore credibility in its work among the scientific community and the public.

We look forward to your answers to these questions.

Finally, we would like to reiterate our demands in relation to the renewal of the EU approval for glyphosate.[xii] We ask the European Commission to:

- Refrain from taking any final decision on the renewal of glyphosate's EU approval as long as uncertainty remains over the risks it poses to human health and environment;

- Immediately ban the use of glyphosate where it results in the greatest public and worker exposure, including non-professional use in gardens and domestic environments, use by municipal authorities, railway and highway networks, and specialised agricultural uses, such as the desiccation of crops.

This letter will be published on the websites of the signatory organisations.

Yours sincerely,

Jorgo Riss, Director,
Greenpeace European Unit

Also on behalf of:
Corporate Europe Observatory
Health & Environment Alliance (HEAL)
Pesticide Action Network Europe
Friends of the Earth Europe
European Environmental Bureau
Avaaz
WeMove

[i] http://ec.europa.eu/commission/2014-2019/andriukaitis/announcements/my-letter-dr-richard-p-garnett-chair-board-glyphosate-task-force-04-april-2016_en
[ii] http://www.efsa.europa.eu/en/press/news/151112
[iii] http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf
[iv] http://goo.gl/tlVYBc
[v] http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf
[vi] http://healthandenvironmentonline.com/2016/02/11/efsa-iarc-and-glyphosate-the-significance-of-the-secret-studies/
[vii] http://goo.gl/9QkssK
[viii] http://goo.gl/EiQGZd
[ix] http://corporateeurope.org/sites/default/files/attachments/4302add_public.pdf
[x] http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full
[xi] http://www.glyphosate.eu/gtf-statements/gtf-proposes-access-all-14-carcinogenicity-studies-reading-rooms
[xii] http://www.greenpeace.org/eu-unit/en/Publications/2015/Glyphosate--Need-for-a-robust-and-credible-scientific-assessment-of-carcinogenicity/

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