Greens seek transparency of glyphosate studies before the European Court of Justice: Press Briefing

10 September 2018

Summary of the Greens/EFA MEPs Court Case vs EFSA, Monsanto and Cheminova

This case concerns the lack of transparency from EFSA regarding the scientific studies they used to assess the safety of glyphosate as part of its approval for sale on the EU market.

Following an access to documents request from 4 Greens/EFA MEPs, EFSA denied us access to key parts of the studies such as the methodology, materials, experimental conditions, the results, discussion of the findings and the conclusions, in order to protect the commercial interests of the study owners.

The Greens/EFA MEPs took EFSA before the European Court of Justice on the 24 May 2017, and EFSA is supported in these proceedings by Monsanto and by Cheminova, which both joined the case on 21 September 2017. **The public hearing in the case will take place in Luxembourg on the 13th September**.

This case is about balancing whether or not the commercial interest of the companies should outweigh the public interest in the information, and also, whether or not the studies can be considered as information about emissions into the environment.

1. Background of the Case

At around the same time that the EU institutions were deciding whether or not to renew the license for glyphosate to be sold on the EU market, the World Health Organisation's cancer agency, IARC, concluded in March 2015 that glyphosate is "possibly carcinogenic for humans". However, in November 2015, EFSA, the EU agency responsible for scientific assessments, reached the opposite conclusion: that glyphosate is not carcinogenic.

When Members of the European Parliament asked EFSA about the differences in these findings, EFSA responded that it had analysed studies that IARC had not used during its assessment. The reason for this is that IARC has a policy of only admitting studies that have published in the scientific literature, whereas EFSA does not have this rule.

This led four Greens/EFA MEPs, Bart Staes (Belgium), Benedek Jávor (Hungary), Heidi Hautala (Finland) and Michèle Rivasi (France), to file a public access to information request in March 2016 under the EU's access to documents rules (Regulation 1049/2001 and the Aarhus Regulation, which is specifically about access to environmental information).

After months of intensive back-and-forth with EFSA (the exchange is online here), we were granted only partial access to sections of the studies that were submitted by the companies seeking authorisation to sell glyphosate in the EU. All sections on methodology, materials and experimental conditions as well as the sections containing the results, discussion of the findings and the conclusions, were removed from all of the studies.

EFSA argues that publishing these sections would harm the commercial interests of the companies and that secrecy is necessary to protect their economic investments and know-how.

On the other hand, we believe that the studies should be made public because:

- The right of access to information is a fundamental human right that should only be restricted in duly justified cases - and this is not one of them.
- The rules on access to environmental information clearly state that the public interest in transparency outweighs the commercial interests of private companies if the information is about emissions into the environment - and glyphosate is, by its nature, an emission.
- There is an overriding public interest that requires publication of this information, evidenced by the fact that the European Parliament set up a specific inquiry committee, by the public furore and widespread media coverage resulting from the Monsanto Papers revelations, by the mobilisation of more than 1 million citizens who signed the European Citizens' Initiative on glyphosate, and by the multiple Court Cases ongoing in the US but also other countries in Europe, to mention a few examples (see below for more).

2. What are the main arguments in the Court Case?

The Court Case concerns 12 studies in which glyphosate was tested on mice and rats, because these are the studies that are most important for assessing the carcinogenic potential of glyphosate and we did not want to overburden the Court. The key points of contention are as follows:

A. Should studies on glyphosate be considered information on emissions into the environment?

If the European Court of Justice decides that they are about emissions into the environment, then the legislation (Aarhus regulation on access to environmental information) is very clear on this point: Even if the commercial interests of a company could be harmed, information related to emissions into the environment must be released.

In this case, EFSA argues that the scientific studies used to assess glyphosate **are not about "actual or foreseeable" emissions into the environment**, because the studies are carried out on mice in labs at high doses and so the conditions of exposure used in the lab tests are not comparable to the exposure of humans and the environment in practice.

We argue that these scientific studies are **specifically conducted in order to assess the impact of glyphosate** on human health and they are crucial for deciding whether or not this emission should be authorised, so it is clearly linked to foreseeable emissions. Going beyond that, **glyphosate is an emission by definition**, which is currently being sprayed on plants all across Europe and the world. Finally, the concept of environmental information also covers information about the effects of emissions as well as information that **allows the public to check** whether or not the assessment of those effects has been carried out properly.

B. Would the Commercial Interest of the Companies be severely damaged by publication?

According to EFSA, the main reason that key parts of the studies are not disclosed is because of the need to protect the **commercial interests of the study owners**. They argue that if the information were to be released, it would undermine their economic investments and know-how, and it could be used by competitors to apply for approvals.

We argue that EFSA never provided reasoning to demonstrate that there would be a harm or even a risk of harm to the commercial interests of the companies, and that they **did not substantiate the existence** of any specific legitimate economic interests. Glyphosate has been on the market for years now, it is already commercialised almost all over the world, and its patent has expired anyway.

C. Is there an Overriding Public Interest in the information anyway?

Under the access to documents regulation (1049/2001), there is a "public interest test" which stipulates that, even if publication could undermine the protection of commercial interests, the information should still be published if there is an overriding public interest in it.

EFSA argues that it has already stuck the correct balance between the protection of commercial interest and the public interest in transparency in this case, by claiming that the information they have already published is enough to allow for independent scientific scrutiny.

However, this is not the case: Toxicology experts have been working with us to review the documentation, and without full access to information about the materials and methods, or the results, discussion and conclusions sections, they **cannot verify the information** found in the tables and annexes to make sure it is actually the outcome of a sound scientific process. Nor can scientists properly replicate the findings.

In addition, the "raw data" received from EFSA still needs to be manually re-entered in order to scan and test the results. When Christopher Portier did this, he discovered **at least 8 cases of statistically significant tumour increases** in the data received, and, in a letter to Juncker dated 29 May 2018, he wrote that "These omissions make it impossible for outside scientists to judge the quality of the studies, the rigor of the methods used to analyze the data, or to determine if there are legitimate reasons in these discussions why the tumors identified ... were excluded".

We believe that the public interest in information about glyphosate is extremely high because:

- There is a **clear potential for conflicts of interest** arising from the fact that the companies applying for market approval are also the ones conducting studies to prove the safety of their products for sale in the EU. Add to that the differences between IARC and EFSA's findings on whether glyphosate is carcinogenic, and transparency becomes indispensible.
- The Monsanto Papers revelations have shown that **Monsanto tried to manipulate scientific studies** in order to fool regulators, and that it ghost-wrote some academic papers in order to get its products approved.
- The European Parliament has adopted **scathing resolutions on glyphosate**, first in April 2016, and then again in October 2017, in which it calling for a phase-out of glyphosate in Europe within the next five years. Parliament also stated that the release of the Monsanto Papers shed doubt on the credibility of some studies used in the EU evaluation on glyphosate safety.
- The controversy around glyphosate has even led the European Parliament **to set up a specific inquiry committee** in February 2018, which has a 9 month term and which has been set up to assess the EU's pesticide authorisation procedure, its independence vis-à-vis the pesticide industry and the transparency of the decision-making, and to put forward specific recommendations for improvement.
- The European Commission announced in December 2017 that it would reform the laws on its assessment processes for glyphosate and **has promised "to change the current rules** to make sure that scientific studies are publicly available".
- Commissioner Andriukaitis himself has previously called on the Glyphosate Task Force (the coalition of glyphosate-producing companies set up to lobby the EU) **to release all data with regard to carcinogenicity** as provided to EFSA.
- An EU Citizens' Initiative was launched in January 2017 that quickly **gathered more than 1,000,000** signatures from citizens in 22 different EU countries.
- Scientific discovery is only possible when results are published along with the methodologies, and when results are also replicable. Otherwise it is not really science.
- Transparency allows citizens to follow, participate in and hold accountable their democratic institutions, and to have confidence in their functioning.

For more information:

- Read a briefing by toxicologists on EFSA's glyphosate transparency: http://extranet.greens-efa-service.eu/public/media/file/1/5195
- Read about Portier's letter to Juncker: http://www.lemonde.fr/planete/article/2017/05/29/glyphosate-et-cancer-des-etudes-cles-ont-ete-sous-estimees-par-l-expertise-europeenne_5135612_3244.html#H2A1ZGQZgeGkctsf.99
- Read our administrative appeal, prior to launching the Court Case: https://www.greens-efa.eu/en/article/news/glyphosate-6945/
- Read our press release and briefing from the day we took EFSA to Court
- Watch our mini-documentary, "Monsanto's Toxic Tricks": https://www.facebook.com/greensefa/videos/monsantos-toxic-tricks/1777997145594462/
- Examine the full correspondence between the Greens/EFA group and EFSA: https://www.asktheeu.org/en/request/is_glyphosate_safe_we_have_the_r