

EFSA statement addressing stakeholder concerns related to the EU assessment of glyphosate and the “Monsanto papers”

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Background

In November 2015, EFSA published its Conclusion on the EU peer review of the risk assessment of glyphosate, an active substance that is widely used in plant protection products¹.

EFSA – in line with the scientific opinion of 27 out of 28 Member State experts – concluded that glyphosate is unlikely to be carcinogenic to humans. This conclusion represented a divergence with the International Agency for Research on Cancer (IARC), which in March 2015 classified glyphosate as probably carcinogenic to humans.

There has been a sustained public debate about the scientific decisions taken with regards to glyphosate since EFSA published its conclusion. The debate intensified in March 2017 after the European Chemicals Agency (ECHA) confirmed EFSA’s opinion.

The recent publication of internal emails by Monsanto in relation to glyphosate (the so-called “Monsanto papers”) has given rise to concerns from some stakeholders and reports in some media that industry improperly influenced the EU assessment of glyphosate, both with regards to the scientific studies used in the assessment and with regards to those who participated in the process.

The nature of the information contained within the “Monsanto papers” was serious enough for EFSA to investigate their significance in relation to the EU assessment of glyphosate. Following this investigation, EFSA can confirm: that there are no grounds to suggest that industry improperly influenced the EU assessment of glyphosate; and that the role of industry and of other actors in the process was carried out according to standard procedures. This statement explains how EFSA arrived at this conclusion.

How does EFSA arrive at the conclusion that industry did not exert improper influence on the EU assessment of glyphosate?

1. Data appraised during the assessment

The EU assessment of glyphosate was based primarily on an analysis of the findings and raw data contained within mandatory guideline studies and on studies published in the open literature, as is the case for all pesticide active substances.

¹ <http://www.efsa.europa.eu/en/efsajournal/pub/4302>

Mandatory guideline studies are paid for by industry and conducted by laboratories certified and audited under 'Good Laboratory Practice' (GLP) standards, an OECD protocol designed to ensure consistency and integrity in chemical safety tests².

The findings of each mandatory guideline study for glyphosate were presented in a detailed study report, which allowed EU experts to check the reliability and quality of the results and decide for themselves which aspects to use in the risk assessment. The integrity of the findings and raw data was guaranteed by the fact that the laboratories carrying out the tests were certified and audited under the GLP system.

There is no information contained within the "Monsanto papers" or that EFSA is otherwise aware of that indicates that industry attempted to falsify or manipulate the findings and raw data of the mandatory guideline studies used in the glyphosate assessment.

2. Industry's position on the safety of glyphosate

The position of industry with regards to the safety of glyphosate was clear to EFSA and Member State experts throughout the peer review process. The EU legislation for pesticides offers the applicant the opportunity to provide its views in the dossier that it must submit to regulatory bodies and at different steps of the peer review process. At no stage were EU experts assessing scientific studies produced, funded, or facilitated by industry without being aware of this connection.

This includes the two scientific review papers by Kier and Kirkland (2013) and Williams et al. (2000) that are mentioned in the "Monsanto papers" and that were considered in the EU assessment of glyphosate. These publications are not original studies but an analysis of mandatory guideline studies included in the applicant's dossier.

Notwithstanding the fact that these two review papers may have been ghost-written by Monsanto – an allegation that if true would constitute a grave breach of scientific and ethical principles – their provenance was evident from the Declarations of Interest and Acknowledgements in the papers themselves.

For example, the Kier and Kirkland paper states that the authors were paid by the Glyphosate Task Force to carry out the review and the Williams et al. paper acknowledges that Monsanto facilitated the authors' work by providing them with original, unpublished studies³⁴. This means that Member State and EFSA experts were under no illusion about the links between the study authors and the companies that funded or facilitated their work when the experts carried out the risk assessment.

Furthermore, the weight of these two review papers was very limited in the overall scientific assessment of glyphosate. This is because EU experts had access to, and relied primarily on, the findings of the original studies and the underlying raw data

² OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring: <http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm>

³ <https://www.ncbi.nlm.nih.gov/pubmed/23480780> (Kier and Kirkland 2013)

⁴ <https://www.ncbi.nlm.nih.gov/pubmed/10854122> (Williams et al. 2000)

to produce their own conclusions. The review papers simply served to summarise or substantiate the industry position on glyphosate that had been presented elsewhere. Finally, the review papers in question represented only two of approximately 700 scientific references in the area of mammalian toxicology considered by EFSA in the glyphosate assessment.

3. The role of Member States and EFSA in challenging the position of industry

In the EU regulatory system for pesticides, the burden of proof of safety lies with the company that seeks to place their products on the market. This system is common to many regulated industries in the EU, including medicines.

In practical terms, this means that applicants are required to present a dossier containing a set of mandatory guideline studies and to carry out a literature review of scientific papers published in the last 10 years, among other requirements. It is the role of Member State and EFSA experts to verify the applicant's proposals, which they do by evaluating the findings and raw data of the mandatory guideline studies and by appraising the studies in the open literature according to a set of uniform scientific principles. In this way, EU experts are able to reach their own conclusion about the safety of the active substance in question.

It is not unusual for Member State and EFSA experts to disagree with industry on how the results of these studies should be interpreted for the risk assessment⁵. This was also true in the case of glyphosate. For example, EFSA dismissed several industry-sponsored studies and identified concerns that led it to conclude that acute health effects should not be disregarded in the setting of Maximum Residue Levels for glyphosate in food.

The EU peer review for the risk assessment of active substances operates on the basis that every scientific study is scrutinised and challenged by EU risk assessors based on the evidence contained within the study. For mandatory guideline studies, EU risk assessors have access to the study report containing the raw data produced by the GLP laboratory.

In the case of glyphosate, EFSA is satisfied that the evidence EU experts had access to was sufficient to allow for a thorough, independent evaluation of the toxicity of the substance and of the possible risks regarding intended uses.

Furthermore, the process was comprehensive (lasting three years and covering hundreds of scientific references), consistent (applied in the same way as for previous assessments), and transparent (with detailed information published on EFSA's website about how every study was appraised).

4. The role of observers in the peer review process

Recently, environmental NGOs have alleged that EFSA dismissed a carcinogenicity study by Kumar (2001) based solely on the testimony of Jess Rowland, a scientist who participated as a US-EPA observer to an expert consultation that EFSA

⁵ Information about the EU authorisation status of active substances can be found in the EU pesticide database: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

organised in September 2015. Emails from Mr. Rowland to Monsanto employees appear in the “Monsanto papers” and he is alleged to have had an improper relationship with industry.

While it is true that Mr. Rowland participated as an observer in an expert consultation in September 2015, EFSA confirms that the experts’ appraisal of the Kumar (2001) study and their overall view that glyphosate is unlikely to be carcinogenic did not change as a result of his intervention.

In fact, the Kumar (2001) study and weaknesses related to its findings were discussed extensively by Member State and EFSA experts prior to the teleconference in September 2015. The information Mr. Rowland provided at the expert consultation in September 2015 merely served to provide additional explanations for the inconsistent results of Kumar (2001) study, which were checked and confirmed after the teleconference by EFSA experts. The US-EPA appraisal of the Kumar (2001) study that Mr. Rowland presented at the teleconference is also confirmed in the organisation’s overall assessment of glyphosate, which it published in September 2016.

It is standard practice for EFSA to invite observers from other regulatory or scientific organisations to its expert meetings. This is to ensure that EFSA is aware of the latest developments around the world in pesticide risk assessment. The role of observers in these meetings is clear: they are not allowed to take part in the drafting process or to take decisions or make recommendations. These rules were upheld for the teleconference in September 2015 that was attended not only by the observer from the US-EPA but also by observers from IARC, the WHO/JMPR and ECHA.

Why should stakeholders have confidence in the EU scientific assessment of glyphosate?

- The assessment of glyphosate was carried out using a comprehensive peer-review process, which is the basis of excellence in science. This process, carried out in line with the EU legislation on pesticides, was thorough and comprehensive, lasting three years and involving almost 100 experts from EFSA and from Competent Authorities in the Member States.
- The peer-review for glyphosate was applied in the same way as it has been for the EU assessment of hundreds of active substances over the last 20 years. This is the same system that has led to many dangerous chemicals having restrictions placed on their use or being removed from the market in the EU.
- EFSA has gone to great lengths to be open and transparent about the EU assessment of glyphosate. It has published its final Conclusion and 6,000 pages of background documents, which include the comments and views of experts offered during the process as well as very detailed information about

how EU experts appraised each and every study and how they evaluated the evidence⁶.

- In response to Public Access to Document requests, EFSA decided to release the findings and raw data from all the genotoxicity and carcinogenicity studies submitted by industry in relation to glyphosate. In doing so, EFSA rejected the vast majority of confidentiality claims submitted by industry and provided the requestors with enough information to allow full independent scrutiny of the EU assessment. As far as EFSA is aware, it is the first regulatory body anywhere in the world to release this amount of information related to pesticide risk assessments.
- EFSA has also presented the glyphosate assessment in a multitude of scientific conferences and further facilitated the scrutiny of the assessment in a review published in a renowned scientific journal⁷.

ENDS

⁶ <https://www.efsa.europa.eu/en/press/news/151119a>

⁷ <https://link.springer.com/article/10.1007/s00204-017-1962-5>