EFSA statement addressing allegations on the renewal assessment report for glyphosate

22 September 2017

Recent reports in the media have alleged that parts of the EU assessment of glyphosate were plagiarised from information provided to regulatory authorities by the companies applying for the re-authorisation of this active substance.

These allegations are unfounded and based on a fundamental lack of understanding of the EU pesticides assessment framework.

“To be clear, the process for the EU assessment of glyphosate was carried out properly, transparently, and in the same way as the assessment of all other pesticides involving EFSA, regardless of whether they lead to market authorisations or to restrictions and bans,” said EFSA’s Executive Director, Bernhard Url.

“In the EU regulatory system for pesticides, which is set out in EU law, the starting point for any risk assessment is a dossier compiled by the company seeking to place an active substance on the market.”

Dr Url added: “It is natural and necessary that parts of the company’s dossier appear in sections of the draft assessment report prepared by the rapporteur member state.”

The dossier submitted by a company to regulatory authorities contains mandatory safety studies, commissioned by the company, and peer-reviewed literature relevant to the active substance in question.

Companies are required to summarise the safety studies and peer-reviewed literature according to set guidelines and provide this information to the regulatory authorities. In a first step, this information is assessed by a rapporteur member state (RMS), which was Germany in the case of glyphosate.

The RMS checks all information provided by the applicant and, where relevant, corrects and amends the applicant’s study summaries and evaluation. If the RMS agrees with a particular summary or evaluation it may incorporate the text directly into the draft assessment report. A close reading of the renewal assessment report (RAR) for glyphosate reveals numerous examples of amendments, modifications and corrections by the RMS of the text submitted by the applicant.

The completion of this first step results in a comprehensive independent evaluation of the applicant’s dossier by the RMS and includes the RMS’s own assessment of the safety of the substance.

Once the RMS has completed the initial risk assessment, it is provided in the form of the draft RAR to EFSA to begin the peer review process, which includes public and expert consultations. The draft RAR has been available on EFSA's website since November 2015.

"Unfortunately, the recent claims appear to be part of an orchestrated campaign and the latest in a series of efforts to discredit the scientific process behind the EU assessment of glyphosate," Dr Url said.

"While of course we welcome all interested parties to scrutinise our work, it is important that the integrity of the legally prescribed scientific process is not purposefully undermined for short-term political gain."

Background

In 2014, EFSA launched a public consultation on the draft RAR provided by Germany, in which all interested parties and the general public were invited to provide comments and additional scientific information pertinent to the safety of glyphosate. The public consultation attracted a large number of comments, all of which are recorded and discussed in the peer review report for glyphosate available on EFSA's website.

In addition to the public consultation, in 2015 EFSA organised an expert peer review on the RAR, which alongside EFSA's own scientists involved more than 70 experts from appointed public organisations (environmental protection agencies, food safety agencies, chemical agencies and others) in all 28 EU Member States and Norway.

The results of the public consultation and the expert peer review were incorporated by EFSA into its final conclusion, which was published in November 2015 and provided to the European Commission and Member States to inform the decisions they take as risk managers at European level.

Documents available on EFSA's website

- EFSA Conclusion on glyphosate
- Final addendum to the renewal assessment report
- Peer review report for glyphosate
- EFSA Conclusion on the endocrine potential of glyphosate
- Details on the carcinogenicity assessment of glyphosate