efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

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Re: **Your request for public access to documents of 15 March 2016**
Ref.: PAD 2016/034

Dear Honourable Members of the European Parliament, Mrs Hautala, Mrs Rivasi, Mr Jávor, Mr Staes,

With regard to your e-mail of 10 June 2016 I'm glad to provide you with the following reply.

In your e-mail you ask EFSA to clarify within ten days whether or not you are entitled to have access to the requested documents and names of the Member State representatives involved in the assessment of glyphosate.

Regarding the former, it needs to be highlighted that EFSA can take the decision whether it is in the position to disclose the studies only in line with the applicable legislation. Besides the legal deadlines under Regulation 1049/2001, on which EFSA engaged with you with a view to seek a solution according to Article 6 of this Regulation, this encompasses the obligation to assess whether any of the exceptions for disclosure are applicable to the requested documents. This assessment is twofold; it comprises a) the purely factual establishment of the extent of the claims in the documents in question and b) the legitimacy of the claims for non-disclosure. Before this fact can be collected and checked, your question must remain pending. To clarify this stage of the process, I am providing you with the exchanges with the companies that submitted the studies to EFSA by 12 July 2016.

EFSA needs the engagement with the companies who submitted the studies to the Authority in order to assert whether partial, full or no disclosure of the studies is possible.

In your email of 10 June 2016, you also sought an estimate of the time it will take to process the original request for the 82 studies. We made an estimation of the timeframe needed to screen the studies against the confidentiality claims and process them under Regulation (EC) No 1049/2001 (PAD Regulation)[1]. The estimation is that it may take approximately up to 1600 working hours to screen the confidentiality claims. It needs to be noted that such estimation is subject to the extent and amount of claims that EFSA will receive.

EFSA's capacity of processing personal data of Member States experts involved in the peer review of glyphosate is impacted by the fact that these experts are nominated by Member States and represent national competent authorities in the Pesticides peer-review experts meetings. This is in stark contrast to the system of scientific panels of EFSA, which is ruled by EFSA's founding regulation and under which EFSA governs the process of selecting experts in their personal capacity and where EFSA has sovereignty over the management of interests of the experts and the publication of their Declarations of Interest. In the absence of a legal basis requiring these national authorities' representatives to submit a DoI, EFSA's scheme to seek Annual DoIs in this case is of a voluntary nature[2]. The same holds true for what regards the publication of any DoI having been submitted by these experts. The legal framework governing the publication of personal data of these experts designated by Member States is therefore Regulation (EC) No 45/2001[3].

For what concerns your request to EFSA of identifying which experts among those who contributed to the peer review process actually worked on the glyphosate dossier, EFSA needs to consult the data subjects in accordance with Article 5 of Regulation (EC) No 45/2001. Such consultation was done previously and you were informed of the outcome on 11 April 2016: EFSA has released a list of Member States organisations and experts' names when the consent was given.

In the absence of consent from the data subjects, EFSA has now assessed the necessity of the transfer of personal data under Article 8 of Regulation (EC) No 45/2001, duly considering the arguments regarding the necessity of the transfer, in relation to public concerns on their independence and impartiality.

As regards independence and impartiality, please note that experts' representatives of Member States organisations coordinate within their organisations the collection of comments before sending them to EFSA. The peer review process is undertaken by experts acting for Member States national authorities, and, contrary to what is the case of the members of EFSA's Scientific Committee and Scientific Panels or their Working Groups, not in their personal capacity. Therefore, EFSA considers that in view of the fact that the experts express corporate views on behalf of their national organisations and that the comments of the organisations are available to the public, the disclosure of the names of the experts deployed to glyphosate is not necessary in order for the public to be able to properly scrutinize the objectivity of the peer review process and its deliverables.

Finally, with regard to the question you raise on the number of the pages of the requested studies, please note that the length of the studies is highly variable, from few pages to thousands. The studies still requested include the most voluminous ones, which

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1 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48.

2 Please also see Article 10 of the Decision of the Executive Director on Declarations of Interests, 31/07/2014, available at: http://www.efsa.europa.eu/en/sites/default/files/assets/independencerules2014.pdf.

3 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8, 12.1.2001, p. 1–22.

means that the reduction in the number of requested studies is not proportional to the reduction in the number of requested pages. Nevertheless, please note that the estimations on equivalent number of pages is just an indication intended to provide a first view regarding the length and size of the studies that need to be screened. We have requested the companies to provide detailed claims on these 82 studies which will clarify the total size of the information subject to the sanitisation process and checked for confidentiality.

With reference to Article 6(3) of the PAD Regulation, we will provide you with an update on the status of your request by **10 July 2016**, after we have received feedback from the entities who submitted studies on our proposal for organising our work. I hope the above addresses your questions and please do not hesitate to contact me if you require any clarification.

Yours sincerely,

Dirk Detken

Cc: J. Tarazona, J. Ramsay, J. Kleiner (EFSA)