

**11 APR 2016**

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**Heidi Hautala**  
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Greens/EFA  
**Benedek Jávor**  
Member of the European Parliament  
Greens/EFA  
**Michèle Rivasi**  
Member of the European Parliament  
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**Subject: 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,

Further to our acknowledgement of receipt of your letter dated 16 March 2016 and the complementary e-mail of 21 March 2016, I am pleased to provide you with a reply to the request for access to documents you submitted jointly under Regulation (EC) No 1049/2001 regarding public access to documents<sup>1</sup> (hereinafter referred to as the "PAD Regulation") and Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention<sup>2</sup> (hereinafter referred to as the "Aarhus Regulation").

With your e-mails of 15 and 16 March 2016, you requested access to "*all documents that have been used during the EFSA peer review. Our request covers complete documents and not only their summaries, and extends also to the names of the authors and their declarations of conflicts of interests*".

<sup>1</sup> 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, applicable to EFSA.

<sup>2</sup> Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 264, 25.9.2006, p. 13-19.

Please allow me for completeness sake to first refer to the documents that fall under your request that have been made public by EFSA concerning the peer review of glyphosate. Together with its conclusions, EFSA published on 12 October 2015<sup>3</sup> the below documents in accordance with the requirements of Regulation (EC) No 1107/2009. You can find the following files on EFSA's website:

- The sanitised supplementary summary dossier, available on the Register of Questions<sup>4</sup>;
- The Renewal Assessment Report (RAR):
  - o The RAR volumes 1 to 3<sup>5</sup>:  
Please consider that volume 2 of the RAR contains the list of studies that the applicants submitted for the first review and for the renewal process. At the end of each chapter of volume 3 you will find the list of studies submitted, including those studies submitted following EFSA's request for additional information.
  - o The revised RAR was published at the end of the peer review and its sanitised version is publicly available.<sup>6</sup>
- The comments of Member States experts involved, are publicly available as part of the peer review report<sup>7</sup>;
- The Meeting reports with experts from the Member States: are publicly available<sup>8</sup>.
- The Final addendum addressing the Mandate from the European Commission on the IARC assessment is publicly available<sup>9</sup>.

Documents which fall under your request for which this is not the case concern documents in the supplementary dossier (in complement to the initial and for the renewal process), studies listed in volume 2 and in volume 3 of the RAR at the end of each chapter.

Please note that EFSA received approximately 1500 studies with the initial dossier and the supplementary dossier, each one counting from 500 to 1000 pages, so the total would equal approximately a range of 700 000 to one million pages of studies submitted by the applicants. Considering this large amount of studies concerned by your request, we would like to clarify whether you seek access to all of them or a selection of them. We seek this reflection in view of the resources it would bind at EFSA screening 1500 studies against the exceptions of the PAD Regulation.

A proposal based on a parallel mail of Mrs Rivasi of 1 April 2016 could be to reduce your access request to the following three studies:

- "Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice" (2001), following OECD Guideline 451 & GLP – study owned by the Israeli pesticides company ADAMA Agan Ltd and was never published;
- "Glyphosate technical: Dietary Carcinogenicity Study in the Mouse" (2009), following OECD Guideline 451 & GLP – study owned by the Australian pesticides company Nufarm and was never published;

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<sup>4</sup> Register of Question, search to be made by substance:  
<http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/bookmarkable/eu.europa.efsa.raw.gui.pages.substance.SubstanceSearchPage?22>.

<sup>5</sup> The RAR is available at the following link: <http://dar.efsa.europa.eu/dar-web/provision>.

<sup>6</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/outputLoader?output=ON-4302>.

<sup>7</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/outputLoader?output=ON-4302>.

<sup>8</sup> Schedule for pesticides peer-review experts meetings, available at:  
<http://www.efsa.europa.eu/sites/default/files/assets/peerreviewexpertsmeetings-da.pdf>.  
Meeting reports available in the peer review report:

<http://registerofquestions.efsa.europa.eu/roqFrontend/outputLoader?output=ON-4302>.

<sup>9</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/outputLoader?output=ON-4302>.

- "HR-001: 18-Month Oral Oncogenicity Study in Mice" (1997), following following OECD Guideline 451 & GLP – study owned by the Japanese pesticides company Arysta LifeSciences Corporation and was never published.

With regard to the above please note that EFSA is already liaising with the studies owners with a view of identifying the margins of disclosure in addition to the summaries already published. Should you confirm your agreement to receive the above studies, we would be able to provide you with a reply once we have finalised the consultations in accordance with Article 4(4) of the PAD Regulation.

In view of the large amount of documents concerned by your request and in view of the pending clarifications on its scope, we regret to inform you that in accordance with Article 6(3) of the PAD Regulation which refers to the possibility for a fair solution in cases where requests relate to a very large number of documents, we will wait for your clarifications on the scope of your request, before fixing a deadline for a reply.

Regarding your request concerning the names and declarations of interests of the authors, we can provide you with the list of Member States' Risk Assessment organisations involved in the peer review of active substances under Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (Annex I).

EFSA liaised previously with the 76 Member States representatives who were involved in the assessment of glyphosate. We requested in line with Regulation (EC) No 45/2001 on the protection of personal data<sup>10</sup> for their views for sharing personal data with the concerned interested parties and with the public, namely the information that they represented their administration in the experts' meetings organised by EFSA in the context of the peer review of the assessment of Glyphosate. The list in Annex I mentions the names of 14 experts who have agreed to release their names as participants to the meetings organised by EFSA in the context of the peer review of the assessment of Glyphosate.

We should specify that only few ADoIs of these Member States representatives that agreed on the disclosure of their names are published on the EFSA's website since the publication of ADoIs of experts' members of Networks is subject to their prior consent at the moment of collection in application of data protection rules and EFSA's Decision on Declarations of Interests<sup>11</sup>.

Please find here the link to the published ADoIs of the Networks' experts:  
<http://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsmeetings>.

In order to comply with rules on personal data protection for the remaining experts involved we refer to the affiliations in the above list.

<sup>10</sup> 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.

<sup>11</sup> Available at: <http://www.efsa.europa.eu/en/sites/default/files/assets/independencerules2014.pdf>.

To exercise your right to appeal against this decision of partial disclosure by a confirmatory application, you may write to EFSA at the address below. You have fifteen working days from receipt of this letter to appeal. Beyond this deadline, your initial request will be considered as fully satisfied. In case you submit a confirmatory application, EFSA will inform you of the outcome of this re-examination of your request within fifteen working days of receipt, either by granting you access to the documents or by confirming the refusal. In the latter case, you will also be informed of any further appeal routes available.

Further correspondence must be sent to:

EFSA

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E-mail: [EFSA.public.access.to.documents@efsa.europa.eu](mailto:EFSA.public.access.to.documents@efsa.europa.eu)

Yours sincerely,



Dirk Detken

Enclosures: 1 Annex

Cc: J. Tarazona, J. Ramsay