

07 OCT 2015

Ref. DD/CP/mm (2015) - out-14719357

Mrs Mute Schimpf, Friends of the Earth Europe

Mrs Faustine Bas-Defossez, European Environmental Bureau

Mr Nikolai Pushkarev, European Public Health Alliance

E-mail: ask+request-2234-21cc5837@asktheeu.org

**Re: Your request for public access to the Renewal Assessment Report (RAR) on glyphosate, revised on 29 January 2015**

Ref.: PAD 2015/93

Dear Mrs Schimpf, Mrs Bas-Defossez and Mr Pushkarev,

I refer to your request for access to documents dated 28 August 2015, by means of which you asked for the Renewal Assessment Report (hereinafter 'RAR') on glyphosate prepared by Germany as Member State rapporteur, as revised on 29 January 2015, in particular:

1. *"Volume 1, Report and proposed decision; The glyphosate renewal assessment report prepared by the German authority Bundesamt fuer Risikoforschung;*
2. *Volume 3, Annex B.6.1 Toxicology and Metabolism. Revised 29th January 2015;*
3. *The glyphosate renewal assessment report prepared by the German authority Bundesamt fuer Risikoforschung, List of Endpoints, Active Substance Glyphosate. Report and Proposed Decision. Revised 29th January 2015".*

We have assessed your request in accordance with Regulation (EC) No 1049/2001 on public access to documents<sup>1</sup> (hereinafter the "PAD Regulation") and we are pleased to provide you a reply as follows:

**1. Your request of the RAR on glyphosate as revised on 29 January 2015**

Please be informed that according to the procedure for the renewal of active substances laid down in Regulation (EC) No 1141/2010<sup>2</sup>, the German RAR on glyphosate in its initial version was published on EFSA's website at the following link: <http://dar.efsa.europa.eu/dar-web/provision/request/subid/562>.

EFSA received the mandate for an EFSA peer review (EFSA Conclusion) on the active substance glyphosate in accordance with Article 16 of Regulation (EU) No 1141/2010

<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> Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, p. 10-19, as last amended.

from the European Commission (M-2014-0226). **The deadline for EFSA to issue its Conclusions is the 30 October 2015.** You can follow the status of the peer-review on EFSA's Register of Questions website<sup>3</sup>.

Thus, EFSA is currently finalising the peer-review of glyphosate and, for this purpose, is taking into account all the subsequent versions of the RAR, among which the one of 29 January 2015, as well as additional documents and reports which are all part of the supporting documents being currently assessed by EFSA, together with the Member States experts. Therefore, at this stage, the requested version of the RAR is a working document which was subject to changes and is being analysed in the framework of the scientific risk assessment (peer-review) phase of the renewal procedure.

In addition, please note that the RAR in all its subsequent versions and its addendum contain commercial sensitive business information from the applicants (glyphosate task force) for which claims for confidential treatment were submitted, in accordance with Article 63 of Regulation (EC) No 1107/2009<sup>4</sup>.

It follows from the above, at this stage, that EFSA cannot give you access to the requested document since its disclosure would undermine EFSA's on-going decision-making process in accordance with the exception to disclosure of Article 4(3), first paragraph, of the PAD Regulation. In addition, this document contains commercial sensitive information which disclosure may undermine the commercial interest, including the intellectual property of applicants, in accordance with Article 4(2), first indent, of the PAD Regulation.

However, please note that, as part of the peer-review process, EFSA will make **publicly available** all the subsequent versions of the RAR as well as the addendum and all supporting documents after the finalisation and adoption of its conclusions (expected for the 30 October 2015), and more particularly, after the sanitisation of the documents against confidential commercial information from applicants, **by the end of the year**. A short informative note on the subsequent steps of the renewal process can be found here: <http://www.efsa.europa.eu/en/press/news/150730>.

Therefore, since the documents subject to the access request will be published after EFSA has finalised its conclusions and following the sanitisation of commercial sensitive information, the refusal to give access is temporal.

Please finally note that neither EFSA nor the European Commission gave access to the revised RAR to anybody, industry or NGOs.

## 2. Confirmatory application

To exercise your right to appeal against this decision of non-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.

<sup>3</sup> Available at <http://registerofquestions.efsa.europa.eu/roqFrontend>. You can search using the EFSA question numbers for the peer-review of glyphosate EFSA-Q-2014-00546 and EFSA-Q-2015-00279.

<sup>4</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1-50, as last amended.

Further correspondence must be sent to:

EFSA

Dirk Detken, Head of the Legal and Regulatory Affairs Unit

Via Carlo Magno 1/A

I - 43126 Parma

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

Yours sincerely,



Dirk Detken

Cc: J. Tarazona (EFSA)

