efsa
European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

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Heidi Hautala
Member of the European Parliament
Greens/EFA
Benedek Jávor
Member of the European Parliament
Greens/EFA
Michèle Rivasi
Member of the European Parliament
Greens/EFA
Bart Staes
Member of the European Parliament
Greens/EFA

European Parliament
Rue Wiertz 60
B-1047 Brussels
Belgium

e-mail: ask+request-2691-d2b30eda@asktheeu.org.

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,

We would like to thank you for your clarification e-mail of 25 April 2016 in which you specified the scope of your initial request for access to documents of 16 and 21 March 2016, submitted under Regulation (EC) No 1049/2001 regarding public access to documents[1] (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[2] (hereinafter referred to as the "Aarhus Regulation").

[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, applicable to EFSA.

[2] 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.

We have analysed your reply and it is our understanding that the scope of your request now covers approximately 30% of your original request, comprising the following documents:

- The fourteen studies in rodents included in the joint submission dossier, including the raw data;
- The historical control data contained within those studies, in particular the historical control incidences for renal tumours and for haemangiosarcoma from the laboratories that performed the mouse carcinogenicity studies cited by EFSA;
- All studies that were assessed by EFSA concerning mechanisms of carcinogenicity such as genotoxicity and oxidative stress in relation to glyphosate and its representative formulation in their entirety;
- Regarding the oxidative stress, please note that the Addendum prepared by BfR following the IARC publication (publicly available as part of the Final addendum), in pages 74 onwards, oxidative stress is assessed. The relevant studies mentioned are publicly available in literature.

Your request now covers 182 studies, among which 100 are available in the open scientific literature. We are enclosing to the present letter the list of these 182 studies that your request concerns with an indication which are publicly available.

Regarding the remaining 82 studies which are not published, EFSA estimates that these represent approximately 100 000 to 300 000 pages. In line with EFSA's legal obligations under the PAD Regulation, to process your request for access to these studies, EFSA is setting up a process to consult the study owners in application of Article 4(4) with a view to assessing the applicability of any of the exceptions to public disclosure foreseen in the PAD Regulation.

Based on the arguments provided so far, it is likely that substantial commercial interests, including intellectual property, will be asserted. In order to follow up on your request, EFSA would need to continue the dialogue with the companies who are owners of the studies. The above is an indication that, given the legal framework EFSA is subject to, your request in its current form will still require considerable time to be processed.

In previous communications with EFSA, you made reference to the existence of an overriding public interest that would be particularly prominent in this case, which is a factor EFSA has assessed. EFSA's analysis is that, in view of the scientific conclusions and background documents adopted and already made publicly available by EFSA, the interest to disclose additionally in full all the studies on which EFSA based its conclusions cannot at this stage be considered to constitute per se a public interest for disclosing the unpublished studies that overrides the commercial interests of the study owners that are under investigation.

Without prejudice to EFSA continuing the processing of your public access request, we would also like to highlight to you potential voluntary solutions that may address the legal and quantitative constraints highlighted above which the study owners seem to be open to, which is the option of a physical reading room. Such access method is an option EFSA would like to seek your views on.

Without prejudice to this question, with reference to Article 6(3) of the PAD Regulation and with a view to establishing a fair solution, we will provide you with a status update on your request within 15 working days, by Wednesday 22 June 2016 at the latest. I trust that this suggestion is agreeable to you and please do not hesitate to contact me if I can provide you with further information.

Yours sincerely,

Dirk Detken

Encl.: I

Cc: J. Tarazona, J. Ramsay, J. Kleiner