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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, Ms Hautala, Ms Rivasi, Mr Jávor, Mr Staes,

Further to my letter of 15 July, I am writing to update you on the status of your request for public access to the studies submitted to EFSA for the peer review of the active substance glyphosate.

As anticipated at our meeting held on 29 September 2016, I am pleased to inform you that EFSA has decided to release the raw data and findings (aggregated in tables and figures) of the unpublished studies which it deems cannot be considered as containing commercially sensitive or proprietary information under the applicable legal framework. Alongside the detailed background information about the peer review of glyphosate that is already available on EFSA's website this release allows you to scrutinise the scientific assessment and reproduce the evaluation of the pesticide carried out by EFSA and EU Member States.

In the sections below (Annex I), you will find more details about how EFSA assessed your access to documents request and what information it has decided to release, as well as the information about your right to appeal this decision as far as the partial refusal is concerned.

We also provide you with the full references of the eight studies already published, in order to allow you to retrieve them (Annex III). These studies were included in the list of studies sent to you on 31 May 2016 and are to be subtracted from the 81 studies initially indicated as 'literature' (published) in this list¹. Two additional studies have been added to the initial list provided to you that were identified as pertinent for your request. These studies were

¹ In previous correspondence 82 studies were initially recorded as part of your request. However the list sent to you counts 101 published studies, so 81 unpublished studies.

identified in separate sections of the Renewal Assessment Report from Germany (RAR) while screening the complete reference in the assessment process of your request and are relevant for the genotoxicity and carcinogenicity assessment. We have included full reference to them in Annex III. These updates change the amount of studies included in your request from 81 to 75².

In line with the indication given to you during the meeting held between us on 29 September 2016, EFSA will start the final phase of processing your request verifying several thousands of pages on 10 October 2016 and commits to sending you the full set of documents within two months i.e. no later than 9 December 2016.

In your letter of 20 July 2016, you requested a number of clarifications on specific studies. I have provided answers to your questions below in Annex I. Enclosed to this letter you will also find the latest release of correspondence between EFSA and the study owners.

I trust that EFSA's decision addresses the substance and motivation behind your request, namely to allow for independent scrutiny of the way in which EFSA and Member States arrived at their scientific conclusions on glyphosate.

Please do not hesitate to contact me if you require any further clarifications.

Yours sincerely,



Dirk Detken

Encl.: Letters from Helm AG and Monsanto

Cc: J. Tarazona, G. de Seze, J. Ramsay

² Please consider that your request concerns the recorded 81 unpublished studies of the list sent on 31 May 2016 to which are to be subtracted eight studies that were actually published. EFSA then is adding two relevant studies. The total number of studies falling in the scope of your request is 75.

ANNEX I: assessment of your public access to documents request

1. Release of the raw data of the unpublished studies used for the peer review of the active substance glyphosate

In line with the applicable EU legislation governing public access to documents, EFSA has balanced your interest in reviewing the studies submitted for the EU peer review of glyphosate against those of the study owners in protecting their legitimate interests.

EFSA has reached the decision to give you partial access to the scientific information used for the peer review on the active substance glyphosate, by physically releasing to you the raw data and findings (aggregated in tables and figures) in its possession in relation to the concerned unpublished studies. This information will allow you to reproduce the evaluation performed by EFSA and, therefore, scrutinise EFSA's scientific assessment in the context of the peer review on glyphosate.

The above decision results from an assessment carried out by EFSA of the confidentiality claims put forward by the study owners on the basis of Regulation (EC) No 1049/2001³ (hereafter referred to as "PAD Regulation"), read in conjunction with Article 63(2) Regulation (EC) No 1107/2009 concerning plant protection products⁴. In particular, the companies owning the studies argued that all information contained in the studies you requested have to be considered confidential because they are subject to the exceptions of the PAD Regulation laid down in Articles 4(2), first indent, (protection of commercial interests, including intellectual property), 4(3), first paragraph, (serious undermining of a decision-making process), and 4(1)(b) (protection of the privacy and the integrity of the individual). Some study owners also maintained that Article 16 of the PAD Regulation protecting documents covered by copyrights would support the claim for confidentiality of the scientific studies.

After a thorough analysis, EFSA concluded that the exceptions raised by the study owners do not apply to the raw data and findings (aggregated in tables and figures) of the concerned studies and, therefore, considers that the claims for non-disclosure are to be rejected.

Please allow me to draw your attention to the fact that the assessment of each study during the EFSA peer review, including the justification for not accepting some studies or some study findings as reliable, has been published in the EFSA Conclusion and background information⁵. These studies are conducted according to the methodology established by standard protocols⁶. EFSA has published summary reports and assessments for each study, together with the background information to the EFSA Conclusion, including deviations from the standard protocols if any. Consequently, by providing you with the raw data and findings (aggregated in tables and figures) of each study, you will have the information required for the additional scientific review of those studies mentioned in your request.

³ 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.

⁴ 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.

⁵ All documents were published on EFSA's website at the following link:
<http://www.efsa.europa.eu/en/press/news/151119a>.

⁶ E.g. the Organisation for Economic Co-operation and Development (OECD) guidelines are available at:
<http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>.

See also, US Environmental Protection Agency (EPA) guidelines at <https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

2. Parts of the studies other than raw data and findings aggregated in Tables and Figures

EFSA has also assessed your request regarding the parts of the studies not containing raw data and findings aggregated in tables and figures, in accordance with the PAD Regulation and Regulation (EC) No 1367/2006⁷ (hereinafter referred to as the "Aarhus Regulation"). In particular, EFSA has balanced your interest in reviewing these parts of the studies submitted for the EU peer review of glyphosate against those that the study owners have in protecting their legitimate interests with the following outcome.

- **As regards the exception of Article 4(2), first indent, of the PAD Regulation concerning the "commercial interests of natural and legal person, including intellectual property"**

Firstly, EFSA's assessment of the presence of commercial sensitive information was carried out, taking due account of Article 63(2) of Regulation (EC) No 1107/2009. This Article contains a non-exhaustive list of sensitive information, the disclosure of which "shall normally be deemed to undermine the protection of the commercial interests" of the individuals concerned. EFSA consulted with the concerned companies and study owners in line with its obligations under the PAD Regulation. Accordingly, the parts of the studies identified by EFSA as falling under that list shall be protected in accordance with Article 4(2), first indent, of the PAD Regulation⁸. This, on the grounds that disclosure of this information is liable to seriously prejudice the commercial and financial interests of the person who is the proprietor of the information, causing serious harm to that person's interest.

Secondly, EFSA considered the commercial interests of the companies in accordance with Article 4(2), first indent, of the PAD Regulation. In this respect, EFSA contends that the exception of Article 4(2) of the PAD Regulation covers information such as "scientific know-how" which is broader than the non-exhaustive list of Article 63(2) of Regulation (EC) No 1107/2009. In particular, this concerns the introduction, which contains administrative information on the study, the materials and methods sections with information on batches and analytical methods⁹. This information deserves protection in as much as access to it has a market value by being relevant for the applicant's development and planning to market the substance on many different markets and whose value is reduced if it did not remain secret. It is therefore an intangible asset that may indeed be used for competitive purposes.

Third, as regards the appendixes and other administrative parts of the studies, bearing the regulatory certification of the studies by dedicated laboratories and including the statement of Good Laboratory Practice (GLP) compliance as well as the protocols followed by the studies owners, EFSA considers this information shall also be protected under Article 4(2), first indent, of the PAD Regulation. The grounds for not releasing these sections of the studies are that these are the credentials that give the raw data its specific value in the context of regulatory market authorisation. The release of these parts bears the concrete risk of competitors using the information for their own commercial interests within the EU and abroad.

⁷ 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

⁸ This consideration is comforted by the meaning of Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which intends to protect all commercially relevant data that were submitted when requesting approval for a substance. The TRIPS Agreement has to be considered when interpreting provisions of EU law, see Case C-431/05, Merck Genéricos Productos Farmacéuticos, ECLI:EU:C:2007;496, paragraph 35.

⁹ For a better understanding of the structure of studies and different sections see Annex II.

Finally, the PAD Regulation has an *erga omnes* effect, which means it is presumed competitors will obtain and exploit the studies for their own commercial advantage, particularly with a view of producing that substance and obtaining authorisations to market that substance on different markets within or outside the EU¹⁰. The costs of such damage are estimated in the millions of Euros by the companies and as such EFSA concludes that the interests at stake deserve protection.

• **As regards the exception of Article 4(1)(b) of the PAD Regulation with regard the protection of the privacy and the integrity of the individual**

This exception is a referral to Regulation (EC) No 45/2001 on the protection of personal data¹¹. EFSA considers this exception shall apply in its entirety to all names and signatures contained in the studies, unless this personal data is already in the public domain. This is confirmed by an explicit reference included in Article 63(2)(g) of Regulation (EC) No 1107/2009 concerning the protection of the names and addresses of persons involved in testing on vertebrate animals.

In the case of glyphosate, it would appear that for a significant number of studies that you request, that authors' names of studies are already in the public domain.

With regards to names and signatures that are not already in the public domain and which therefore will not be disclosed, EFSA will only be able to balance the interests at stake and to consider the disclosure of personal data after you have provided an express and legitimate justification in order to demonstrate the necessity of having personal data transferred to you. This is in line with the settled case law of the Union Courts¹². Should you confirm your interest in obtaining this information, you may want to file a confirmatory request filing the justification of the necessity of having the personal data transferred to you.

• **About the existence of an overriding public interest**

EFSA has specifically undertaken the balance of interests at stake in accordance with the PAD and Aarhus Regulations, and concluded that no overriding public interest in disclosure applies to this request

EFSA considers that public interest cannot be presumed overriding or prevailing over the reasons justifying the refusal of the parts of the documents not disclosed. The scientific risk assessment of the safety of the active substance glyphosate conducted by EFSA concluded that the high level of protection required under Regulation (EC) No 1107/2009 can be achieved through the application of available risk mitigation measures, and that the toxicological reference values proposed by EFSA offer a sufficient margin of exposure to cover all identified hazards, including the effects considered as a concern in the assessments of other scientific organisations. In addition, and although the full re-assessment is on-going at EU level, EFSA has conducted three complementary assessments of the potential risks for consumers and has not identified exceedances of the proposed reference values or other concerns regarding public health. Therefore, *per se*, the argument linked to the protection of public health cannot alone justify disclosure of the protected information in the studies.

As regards your argument related to the need to have an additional contradictory assessment of EFSA's peer review, aside from the fact that such a governance option is not provided for by

¹⁰ For example, the section concerning the method relates to the analysis and the manufacturing process contains know-how and the strategy of the companies which is the intellectual property of a certain value and which is not necessarily the information corresponding to the Article 63(2) catalogue. The last sections of the studies dedicated to the certification of a study, the laboratories involved, is information that could be misused by competitors to submit the studies as if another company owned them.

¹¹ 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.

¹² See Judgment in Case C-28/08 P, *European Commission v The Bavarian Lager Co. Ltd.*, ECLI:EU:C:2010:378.

the EU legislators in the adoption process of the underlying legal framework applicable to active substances, please be informed that, in addition to EFSA and EU Member States' competent organisations involved in the EFSA peer-review, the same studies¹³ have been also reviewed and considered by several other regulatory authorities worldwide, and recently by the experts from the FAO/WHO Joint Meeting on Pesticides Residues¹⁴. All these bodies reached a conclusion in line with the EFSA assessment on glyphosate carcinogenicity.

In addition, as regards the need for effective democratic control or the wider control of EFSA scientific soundness, it should be noted that EFSA makes its reasoned conclusions publicly available which, in addition to the disclosure of raw data and findings (aggregated in tables and figures) of the studies detailed in point 1) of this Annex, addresses this need.

Based on the above, EFSA considers that the information to be released to you (i.e. the raw data and findings aggregated in Tables and Figures of the concerned scientific studies) satisfies the need of the public to know and allows the reproduction of the assessment, while protecting the interests and rights of the study owners and authors, thereby reaching a proportionate balance of all the interests at stake.

As regards, the "Aarhus Regulation", the first sentence of Article 6(1) thereof lays down a legal presumption that an overriding public interest in disclosure exists where the information requested relates to emissions into the environment, except where that information concerns an investigation, in particular one concerning possible infringements of Union law¹⁵. In this respect, it must be determined whether the sections of the studies not released to you contain information relating, sufficiently directly, to emissions into the environment¹⁶.

EFSA is of the opinion that not every connection between information and the release of substances into the environment can result in the application of the emissions clause of the "Aarhus Regulation"¹⁷. EFSA considers that the sections of the studies not disclosed do not contain information on emissions of plant protection products or its residues into the environment. The protected sections of the studies neither contain information on emissions, discharges or other releases nor information on the impact of actual emissions or discharges of glyphosate on the environment. Therefore, the presumption laid down in Article 6(1) above is as such not applicable.

EFSA is aware that the definition of emissions into the environment and the interpretation in conformity with fundamental rights and the TRIPS Agreement is under review at the Court of Justice¹⁸ and will adapt its approach to the final ruling once available.

3. Your right of appeal

To exercise your right to appeal 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

¹³ The Joint FAO/WHO meeting on pesticides (JMPR) residues asked industry and received all studies.

¹⁴ Please see the work of the JMPR at the following link: <http://www.who.int/foodsafety/fag/en/>.

¹⁵ Judgment of the General Court of 9 September 2011 in Case T-29/08, *LPN v Commission*, ECLI:EU:T:2011:448, paragraph 108.

¹⁶ So far Union Courts have clarified that residue studies and field trial reports containing information on residues of plant protection products in or on plants such as lettuce constitute information on releases affecting human health if excess levels of those residues are present. See judgment of the Court of 16 December 2010, in Case C-266/09, *Stichting Natuur en Milieu and Others*, ECLI:EU:C:2010:779, paragraph 42.

¹⁷ Information on the release of substances and information on the consequences of such release may be considered as emissions into the environment Opinions of Advocate General Kokott, in Case C-266/09, *Stichting Natuur en Milieu and Others*, ECLI:EU:C:2010:546; and in Case C-673/13 P, *Commission v Stichting Greenpeace Nederland and PAN Europe*, ECLI:EU:C:2016:213, paragraph 30, 35.

¹⁸ Appeal Case before the Court of Justice C-673/13 P, *Commission v Stichting Greenpeace Nederland and PAN Europe*.

satisfied. In case you submit a confirmatory application, EFSA will inform you of the outcome of the 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.

EFSA
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4. Your request for clarification of 20 July 2016

Finally, as regards the list of studies we enclosed to our letter of 31 May 2016, which is an extract of the RAR from Germany, please note that studies that are not published are not necessarily claimed data protected. The companies did not publish all studies for which no data protection was requested. Indeed, claims for confidentiality under Article 63(2) of Regulation (EC) No 1107/2009 are independent from requests for data protection under Article 59 of the same Regulation. Please note that raw data and findings (aggregated in tables and figures) of the unpublished studies will make part of the information we are going to release.

As concerns the correspondence between EFSA and the companies / studies' owners, we are pleased to complement the documents already disclosed, by releasing the final position from Helm AG dated 15 July 2016 and an additional exchange with Monsanto. Please note that personal data (i.e. names of individuals and other personal data such as hand-written signature) present in the correspondence, have been masked in accordance with Article 4(1)(b) of Regulation (EC) No 1049/2001 and Article 8(b) of the Data Protection Regulation (EC) No 45/2001.

Annex II: Study design and sections released

Generic structure of the regulatory study reports conducted under Good Laboratory Practices (GLP) with the indication on the raw data to be released.

| Report structure and sections¹⁹ | Confidentiality assessment |
|---|--|
| Study Title | Disclosed. Only Article 63(2) and personal data will not be disclosed |
| Introductory and administrative pages. GLP statements | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment. |
| Table of content | Disclosed. Only Article 63(2) and personal data will not be disclosed |
| Summary | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as a redacted summary and the EU study assessment are already published. |
| Introduction/Background | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as a redacted summary and the EU study assessment are already published. |
| Material, experimental conditions, methods | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as these are guideline studies, for which the methodology is available and the relevant methodological details and deviations are included in the redacted summary and the EU study assessment already published. |
| Other administrative GLP sections (e.g. archives) | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment. |
| Results/Discussion/Conclusions | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as the section presents the views of the study authors, not EFSA views. The EU study assessment is already published. |
| Tables with aggregated data | Disclosed. Only Article 63(2) and personal data will not be disclosed |
| Figures with aggregated data | Disclosed. Only Article 63(2) and personal data will not be disclosed |
| Appendices/Annexes with raw data | Disclosed. Only Article 63(2) and personal data will not be disclosed |
| Certificates/Statements and other administrative appendices | Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment. |

¹⁹ Note: The Table of Content and the section titles may have different structures and subtitles in the different studies.

Annex III: Additional studies published with references

| N° in EFSA List | Annex point/reference number | Author(s) | Year | Title source (where different from company) report no. GLP or GEP status (where relevant), published or not BVL registration number | Data protection claimed Y/N | Publication |
|-----------------|---|---|------|---|------------------------------------|--|
| 47 | KIIA 5.4.4 KIIA 5.10 (OECD) | Coutinho do Nascimento; A. C.; Grisolia, C. K.; | 2000 | Comparative analysis between micronuclei tests in mice and in peripheral erythrocytes of <i>Oreochromis niloticus</i> in evaluation of mutagenic potential of the agrotoxins deltamethrin, dicofol, glyphosate, and Imazapyr ASB2013-11477 | N | Pesticidas: R. Ecotoxicol. e Meio Ambiente, Curitiba, 10 (January/December 2000), pp. 41-48 |
| 65 | KIIA 5.4.4 KIIA 5.10 (OECD) | Kaya, B.; Creus, A.; Yanikoglu, A.; et al.; | 2000 | Use of the Drosophila wing spot test in the genotoxicity testing of different herbicides ASB2013-9832 | N | ASB2013-9832 Environmental and Molecular Mutagenesis 36: 40 -46 (2000) |
| 76 | KIIA 5.4.4 KIIA 5.10 KIIIA1 7.6.3 (OECD) | Martinez, T. T.; Brown, K. | 1991 | Glyphosate: Oral and pulmonary toxicology of the surfactant used in Roundup herbicide Z80636 | N | Proc. West. Pharmacol. Soc. 34: 43-46 (1991) |
| 77 | KIIA 5.4.4 KIIA 5.11 (OECD) | Mensink, H.; Janssen, P.; WHO | 1994 | Environmental health criteria 159, Glyphosate TOX9500301 | N | <i>Document is available here (i.a.):</i> http://scholar.google.de/scholar?q=Environmental+health+criteri+a+159,+Glyphosate++Mensik+Janssen+W HO&hl=de&as_sdt=0&as_vis=1&oi=scholar&sa=X&ved=0ahUKEw jw3uWBrLTOAhVC1Bo KHX52DAwQgQMlHZA A (2016-08-09) |
| 109 | KIIA 5.5 (OECD) | Anon. | 2015 | Lesion-related incidence data. RITA database ASB2015-2532 | | Please find more information about the RITA database here: http://reni.item.fraunhofer.de/reni/public/rita/ (2016-08-09) Please negotiate access under: e-mail: rita.info@item.fraunhofer.de (2016-08-09) |

| | | | | | | |
|-------|-----------------------------------|---|------|--|---|---|
| 111 | KIIA 5.5 (OECD) | Giknis, M. L. A.; Clifford, C. B.; | 2010 | Spontaneous neoplastic lesions in the CrI:CD1 (ICR) mouse in control groups from 18 month to 2 year studies Selected pages ASB2015-2529 | | Article available here: http://www.criver.com/files/pdfs/rms/cd1/rm_rm_r_cd1_mouse_tox_data_2010.aspx (2016-08-09) |
| 164 | KIIA 5.5.3 KIIA 5.10 (OECD) | Nordström, M.; Hardell, L.; Magnuson, A.; Hagberg, H.; Rask- Andersen, A. | 1998 | Occupational exposures, animal exposure and smoking as risk factors for hairy cell leukaemia evaluated in a case-control study TOX1999-687 | N | Br J Cancer (BJC). 1998 Jun; 77(11): 2048-2052. TOX 1999-687 |
| 172 | KIIA 5.5.3 KIIA 5.10 (OECD) | Séralini, G.- E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendômois, J.; | 2012 | Long term toxicity of a Roundup herbicide and a Roundup- tolerant genetically modified maize. Food and Chem Toxicol., in Press, ASB2012-15514 | N | Environmental Sciences Europe - Bridging Science and Regulation at the Regional and European Level 2014 26:14; Please note: republished after paper was withdrawn from the original publication in Food and Chemical Toxicology, in Press |
| Added | KIIA 5.10 (OECD) | Kitazawa, T. | | IET historical control data on malignant lymphoma incidence in control ICR (Crj:CD-1) mice HR- 001: Carcinogenicity study in mice (IET 94-0151) 13-C015 ASB2014-9146 | | |
| Added | KIIA 5.6.2 (OECD) | Wood, E. | 2011 | Glyphosate Technical: Dietary carcinogenicity study in the mouse – Amendment SPL 2060-0011 ASB2014-9149 | | |