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Re: Your confirmatory application submitted on 10 January 2017

Ref.: PAD 2017/005 CA

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

Further to your confirmatory application for public access of 10 January 2017, submitted under Article 7(2) of the Regulation (EC) No 1049/2001¹ (hereafter referred to as "PAD Regulation") we are pleased to provide you with a reply as detailed below.

Your confirmatory application concerns specific sections of the requested unpublished study reports on the genotoxicity and carcinogenicity of glyphosate not disclosed to you with the EFSA reply dated 7 October 2016 (PAD 2016/034) providing access to the raw data and findings (aggregated in tables and figures). The unpublished study reports at stake were submitted to EFSA for the peer review of the active substance glyphosate under Regulation (EC) 1107/2009 concerning

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.

plant protection products² (hereinafter the “PPP Regulation”). You provide detailed reasoning contesting the partial release with regard to the following sections of the study reports and personal data listed below:

- “materials, experimental conditions and methods”,
- “results and discussion”,
- “statements of Good Laboratory Practice” (GLP statements);
- “names of the Member States experts and their declarations of conflicts of interests”.

1. Your confirmatory application to access three sections of the study reports: “material, experimental conditions and methods”, “results and discussion” and the GLP statements

Your particular interest with regard to the sections on (1) materials, experimental conditions and methods and (2) results and discussion is based on the claim that this information is at the “core of the controversy around whether or not glyphosate should be classified as a probable carcinogen”, you included as specific examples:

- The chemical purity of the tested substance,
- The statistical method: most appropriate for the analysis of the results established before commencing the studies (section on materials, experimental conditions and methods),
- origin of the animals used (section on materials, experimental conditions and methods),
- pathology report: to verify potentially speculative, claims with regard to viral infections, and to check the evaluation of observed tumors (sections on results and discussion),
- Dismissals based on “excessive toxic effects” (section on results and discussion).

You also confirmed your interest to have access to the (3) GLP statements.

In line with EFSA’s obligations deriving from the Union legislation, a full reassessment of the first reply was done, analysing your arguments and balancing the interests at stake.

As you may be aware the study reports were submitted by the applicants organised under the so—called Glyphosate Task Force (GTF) to the rapporteur Member State Germany and EFSA. The GTF represents only certain companies producing glyphosate, not covering all the competing companies in the Union market and worldwide which are interested by the marketing of the active substance. In this respect, it is also important to highlight that the active substance in question may be used and marketed in multiple commercial products under different names or brands.

As indicated in Annexes I and II to EFSA’s letter of reply dated 7 October 2016, the three sections of the study reports, in the scope of your confirmatory application, were not disclosed in order to protect the economic investment of the study owners and the know-how of the companies. EFSA also clarified in its first reply that those sections were not relevant to perform an independent scientific scrutiny of the EFSA assessment. EFSA would like to reiterate this point as the raw data and findings disclosed to you complements the information already published by EFSA and allows to redo the assessment and scrutinise the EFSA peer review.

² 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.

EFSA has reassessed the decision regarding these parts of the study reports and has concluded that by releasing these sections, in addition to the raw data and findings released, the only remaining protected parts would be the introductory and administrative pages part, introduction/background and some certificates and administrative appendices. EFSA considers that the combination of the summaries (already published), the sections already disclosed and the additional sections requested in your appeal, would be sufficient for jurisdictions outside the EU to allow a competitor to submit the studies and include them in a pesticide dossier as free of study owner's rights without undergoing data sharing agreements. In this re-assessment, EFSA has considered not only the information provided to you under this PAD request but also the information previously published by EFSA, in particular the summary dossier and the background information to the EFSA Conclusion which in total represent over 10 000 pages on the glyphosate assessment of published information available for public scrutiny. This notwithstanding, EFSA is herewith addressing the statements of your confirmatory application as follows and provides additional information. As your main concern is on carcinogenicity, we have included in **Annex I** a table with summary information and the indication of the pages of the published documents where you will find the description for the different elements mentioned below.

- **Section on "material, experimental conditions and methods"**

As far as the section of the study reports on "material, experimental conditions and methods" is concerned, please note that these sections of the study reports are explained in the Renewal Assessment Report (RAR) drafted by the Rapporteur Member State Germany, together with the co-rapporteur Member State Slovakia. This information is already in the public domain in a summarised form. However, the full description of the material, experimental conditions and methods is deemed by EFSA as commercial sensitive information warranting the economic investment of the applicants as well as containing know-how.

As regards the **chemical purity of the tested substance**, please note that information on the purity of the tested compound, the relevant impurities and the comparison of the tested compound with the technical specifications of the active substance, as identified during the EFSA assessment, is already publicly available in the background documents published in 2015³. We therefore consider this information as already provided to you. In **Annex I** you will find the specific indications for the carcinogenicity studies.

With regard to the **statistical method** you mentioned as part of this section, please be informed that the actual description of the statistical method of each study is also publicly available in the summaries of the studies in the RAR. We therefore consider this information as provided to you and to the public. In **Annex I** you will find the specific indications for the carcinogenicity studies.

As per the **origin of the animals used** please consider that, contrary to your assumption, the origin of the animals is not related to the historical control information. The information on the historical control has been already provided with the raw data and findings. The information on the origin of the animals used is included in the studies, in most of the cases, but without link to the historical control. The information on the origin of the animals used is part of this section of the study reports which are protected in full as indicated below.

Regarding your objection against the protection of the "methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant", as per **Article 63(2)(d) of the PPP Regulation**, please note that, as stated in the EFSA Conclusion, N-nitroso-glyphosate and formaldehyde were considered

³ See all the information available at: <http://www.efsa.europa.eu/en/press/news/151119a>.

relevant impurities at a maximum content of less than 1 mg/kg and 1 g/kg respectively. Following the agreement for narrowing down the scope of your request for access to documents, EFSA considered for processing your request "all studies used by EFSA to assess carcinogenicity of glyphosate and its representative formulation in their entirety" and "all the historical control data" of glyphosate⁴.

Please note that the information related to the **methods for the analysis of impurities** is reported in a different part of the dossier. In this context we would like to highlight that the description of the method for analysis is already available under **section B.5 of the revised RAR published in 2015** as background document to the Conclusion. The table of content with the list of studies for this section is on page 400 of the published document⁵. If you are interested in the methods of analysis for these two impurities, N-nitroso-glyphosate and formaldehyde the Authority would be able to extract the relevant studies from this different part of the dossier upon confirmation from you that you are also seeking access to these studies. For a better reading, we have extracted the published list of the studies concerned and have enclosed it to the present letter (**Annex II**). As you will notice, some of these studies are publicly available on Internet or have been published in the scientific literature. We therefore consider that these documents have been either provided to you or were not part of the scope of the current confirmatory application.

It follows from the above that the information you are asking for, in relation to this section of the study reports, is already publicly available. EFSA did not include it in the section of the study reports released to you since cross-reference verifications with the information publicly available is possible for each of the study reports at stake.

Furthermore, following the re-screening of this section on material, experimental conditions and methods in each study report, following your confirmatory request, having broken down all the parts on which you manifested an interest, I confirm the position of the first reply of the need to protect this section **in full** under Article 4(2), first indent, of the PAD Regulation, as detailed here below under point 2.

• **Section on GLP statements**

With reference to Directive 2004/9/EC on GLP,⁶ you argue that the GLP statements section of the study reports shall be released to you. However, it has to be pointed out, first, that the Directive on GLP is applicable to Member States for the purpose of national level controls on "organisational processes and conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing of chemicals for the protection of man, animals and the environment"⁷. It is indeed under this legislative framework that Member States do ascertain the quality of the test data generated by companies and laboratories.

EFSA is therefore the recipient of studies which were conducted according to the methodology established by standard protocols⁸ and which were controlled at national level in accordance with this Directive. However, it has to be pointed out

⁴ Your e-mail sent on 25 April 2016.

⁵ You can access the RAR at the following link:
<http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?0-1.ILinkListener-outputForm-outputDocumentsContainer-documents-2.fileNameLnk>.

⁶ Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP), *OJ L 50, 20.2.2004, p. 28-43*, as last amended.

⁷ Recital (2) of Directive 2004/9/EC.

⁸ 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>.

that this information is *not* transferred to EFSA with the application dossiers under PPP Regulation.

Therefore, EFSA is not in the possession of the information requested as described in the Directive on GLP⁹.

As regards the GLP Statements included in the requested study reports, EFSA considers that they are part of the information which deserves protection, under Article 4(2), first indent, of the PAD Regulation, as described below under point 2.

▪ **Section on Results and discussion**

With the published summaries, the **results** of the study reports are explained in the RAR drafted by the Rapporteur Member State Germany, together with the co-rapporteur Member State Slovakia. This information is already in the public domain in a summarised form. However, the full description of the results obtained is deemed by EFSA as commercial sensitive information warranting the economic investment of the applicants.

As per the information on the "**pathology report**, potentially speculative, claims with regard to viral infections, and evaluation of observed tumours" you requested, please note that all raw data in EFSA's possession have been already released to you, including the raw data connected to the information on pathological findings. Therefore, you were already provided access to the related documents held by EFSA.

As regards the "**dismissals based on excessive toxic effects**, please note that the assessment of excessive toxicity is done using the weight of evidence approach. The raw data on all available studies have been already provided to you, and the actual manner in which EFSA weighted the available scientific evidence in the concrete case is described in detail in the conclusion and background documents. Therefore, this information requested is also in your possession.

2. The exception of Article 4(2), first indent, of the PAD Regulation concerning the "commercial interests of natural and legal person, including intellectual property" applies to the requested sections

It is settled case law that the system of exceptions laid down in Article 4 of the PAD Regulation, particularly in paragraph 2 thereof, is based on a balancing of the opposing interests in a given situation.¹⁰

As regards the remaining documents not released to you, EFSA confirms its refusal of the **three sections in full** of the study reports at stake after having thoroughly considered your interest and the obligation of a restrictive interpretation deriving from the PAD Regulation.

Accordingly, after a thorough screening of each study report, the three sections of the studies at stake were identified by EFSA as needing protection in full, in accordance with Article 4(2), first indent, of the PAD Regulation¹¹. This, on the grounds that disclosure of this information is liable to seriously prejudice the commercial and financial interests of the companies having submitted the study reports for the renewal of the approval of the active substance glyphosate. Indeed

⁹ Directive 2004/9/EC, Article 4: "The names of laboratories subject to inspection by a designated authority, their GLP compliance status and the dates upon which laboratory inspections or study audits have been conducted shall not be considered to be confidential."

¹⁰ Cases C-514/11P and C-605/11 P, *LPN and Finland v Commission*, EU:C:2013:738, paragraph 42.

¹¹ 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.

the “commercial interest, including intellectual property” of the companies having submitted the study reports still exists after reassessment of your request, the studies having a value in the on-going renewal approval process and any approval process worldwide.

EFSA has balanced between your expressed interests as Members of the European Parliament to scrutinise and reproduce the scientific risk assessment undertaken by EFSA for drafting its Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate¹² against the interests of the owners of the studies requested having made an important economic investment to produce the studies at stake for the application for renewal of glyphosate as an active substance.

EFSA has concluded that the scientific scrutiny can be performed based on the raw data and findings already disclosed to you and the published documents, in particular with regard to the information requested in the sections on “material, experimental conditions and methods” and “results and discussion”, pointed out in your confirmatory application.

EFSA re-confirms its position detailed in the first reply to you, that the exception of Article 4(2) of the PAD Regulation covers information such as “scientific know-how” and the economic investment of the study owners which is broader than the non-exhaustive list of Article 63(2) of Regulation (EC) No 1107/2009. This concerns:

- the introduction, which contains administrative information on the study, the materials and methods sections with information on batches and analytical methods, results and discussion: information being relevant for the applicant’s development and planning to market the substance on many different markets;
- the appendixes and other administrative parts of the studies, bearing the regulatory certification of the studies by dedicated laboratories and including the GLP Statements of self-compliance as well as the protocols followed by the studies owners: information which constitutes the credentials that give the raw data released to you its specific value in the context of regulatory market authorisation.

In particular, EFSA reiterates that the section concerning the material, experimental conditions and 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 highly likely will be misused by competitors to submit the studies as if they were available for free use for regulatory purposes. The companies having submitted these studies for the renewal of approval of glyphosate still consider those studies of regulatory and economic relevance, so their release bears a concrete risk of damaging their competitive position.

Therefore, by releasing to you the three sections requested, EFSA risks to disclose enough information which, put together with the raw data already released to you, delivers substantial part of the study reports reducing considerably the economic value of the studies at stake, leaving the investment of the study owners unprotected. The release of the two sets of information would reveal the key information of the study reports which allows their use for competitive purposes, affecting not only the applicant’s development and planning to market the

¹² EFSA, 2015, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302, available at: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf>.

substance on many different markets, but also deprive them of the possibility to control the use of their studies for regulatory authorisations, in the framework of data sharing agreements implying a financial compensation based on the cost of the studies.

3. No overriding public interest with regard to the exception of Article 4(2), first indent, of the PAD Regulation

EFSA has re-verified whether there is an overriding public interest justifying the disclosure.

In this EFSA took account of the EFSA Conclusion and background information published in compliance with the legislative requirements, the first decision on 7 October 2016 of partial release of a large amount of the raw data and findings (aggregated in tables and figures) of the study reports requested, the present decision indicating to you where to find the information requested in the published documents, the number of documents having been published in order to support and explain the EFSA's peer review¹³ as well as events organised¹⁴.

EFSA considers that the public interest to have a thorough knowledge of the work done on the peer review of glyphosate for the renewal process of the active substance glyphosate is met by having published a number of documents, including additional specific information on the peer review¹⁵ and by having organised a series of events explaining, in particular, the differences with the hazard assessment performed by the International Agency for Research on Cancer (IARC). The interest for the possibility of performing a full-fledged review of the scientific reasoning and calculations in EFSA's output was also addressed with the release of the raw data and findings of the studies requested without undermining the commercial interest of the companies having invested in the studies and having submitted them for the purpose of the renewal of the approval of glyphosate as an active substance under the PPP Regulation.

It is settled case law that there is a requirement that an applicant has to rely on specific circumstances to show that there is an overriding public interest to justify the disclosure of the documents¹⁶. However, EFSA contends that you have not substantiated how the sections masked are of particular overriding public interest in view of the already disclosed raw data as well as the available published information allowing undertaking a complete public scrutiny of the EFSA's peer review process.

It results from the above that no overriding public interest is deemed to exist in the present case under the PAD Regulation.

Finally, kindly note that EFSA has decided not to unmask the information publicly available that you requested (page 1 of your letter: purity of the tested compound,

¹³ See for example the Fact Sheet on glyphosate at: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate15112en.pdf.

See also the correspondence with IARC published at: <http://www.efsa.europa.eu/en/press/news/160113>.

¹⁴ See Workshop entitled "EU's pesticide risk assessment system: The case of glyphosate": [http://www.europarl.europa.eu/RegData/etudes/STUD/2016/587309/IPOL_STU\(2016\)587309_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2016/587309/IPOL_STU(2016)587309_EN.pdf).

¹⁵ See also the explanation available at: http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf; and <https://www.efsa.europa.eu/sites/default/files/Glyphosate-infographic.pdf>.

¹⁶ Case C-514/11P and C-605/11 P, *LPN and Finland v Commission*, op. cit., paragraph 94.

statistical method and the results)¹⁷ from these sections of the study reports. This decision is based on considerations of proportionality and sound financial management deriving from EFSA's Financial Regulation. EFSA considers that since the information requested is publicly available, although in other documents, the redaction of the huge amount of documents would be a disproportionate use of public resources which will need to be withdrawn from other relevant tasks of EFSA¹⁸, with no added value as the information is already publicly available.

In the spirit of Article 6 of Regulation 1049/2001 we herewith seek your agreement via a fair solution to withdraw this part from your confirmatory application. In this context EFSA would like to offer the following service: in view of the above-mentioned fact that all information to scrutinise the EFSA decision is publicly available, EFSA would like to offer you or your delegates support in exercising such scrutiny by providing scientific support in using the available data. We hope that you will accept this offer and are looking forward to detail the support that EFSA could provide.

4. No overriding public interest in disclosure of the sections of the study reports protected, in application of Article 6(1) of Regulation (EC) No 1367/2006 – no qualification as “emissions into the environment”

EFSA has assessed your request regarding the sections of the study reports not released to you, in accordance with the Regulation (EC) No 1367/2006¹⁹ (hereinafter referred to as the “Aarhus Regulation”). EFSA has taken in consideration the recent judgements of the Court of Justice clarifying the scope of application of Article 6(1), first sentence, of the Aarhus Regulation, constituting an irrebutable presumption on the existence of an overriding public interest when information “relates to emissions into the environment”.

According to the first sentence of Article 6(1) Regulation (EC) No 1367/2006, an overriding public interest, as regards Article 4(2), first and third indents, Regulation (EC) No 1049/2001, is only deemed to exist where the information requested relates to “emissions into the environment”.

The Court's reasoning in its judgements in Cases C-673/13 P²⁰ and C-442/14²¹ confirms EFSA's position that the study reports at stake do not relate to “emissions into the environment”. While the Court rejected a restrictive interpretation of the concept of “emissions into the environment”, it also clarified the limits of that concept. Indeed the Court found that only information actually relating (not only linked) to actual or foreseeable emissions into the environment under normal or realistic conditions of use of that product or substance²² belong to the concept of emissions into the environment. Applying this clarification to the studies at stake, this means that only information or studies replicating the conditions under which the authorisation to place that product or substance on the market was granted and which prevail in the area where that product or substance is intended to be used belong to this concept. EFSA considers that the study reports protected by EFSA in its decision do not fulfil the conditions identified by the Court in these rulings, and therefore may not be regarded as information covered by Article 6(1), first sentence, Regulation (EC) No 1367/2006. It should be highlighted that the Court

¹⁷ From the list of information you asked on page 1 of your letter, as explained under point 1 of the present letter the information on, (1) origin of the animals used, (2) pathology report, (3) dismissals based on excessive toxic effects, was released to you with the raw data.

¹⁸ Please consult the EFSA programming document at: <http://www.efsa.europa.eu/sites/default/files/mb161214-i13.pdf>.

²⁰ Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, EU:C:2016:889.

²¹ Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting*, ECLI:EU:C:2016:890.

²² Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting*, para. 89. Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, ECLI:EU:C:2016:889, para. 71-76.

has not yet decided specifically on the application of Article 6(1) of Regulation (EC) No 1367/2006 to comparable documents, and the above represents EFSA's view on the way the rulings should be applied.

EFSA's position above is grounded on the actual characteristics of these studies. Indeed, the study reports at stake do not concern the exposure of humans to glyphosate following the release into the environment (such as residues information) or its use as plant protection product (sprayed substance). Furthermore, they are not based on the dosage authorised to be used as plant protection product²³. Such documents do neither belong to "emissions" as such ("actual emissions", so information on the quantity, date and place of the emissions into the environment) nor to the effects of emissions ("foreseeable emissions", information relating to the use of the active substance under normal realistic conditions of use).

This means that the study reports deal with a situation which is neither realistic nor covered by the approval. The study reports are based on tests where exaggerated doses were used to feed vertebrate animals so as to test the level as from which the substance is toxic, in order to derive the safe and much lower level of use of the substance which can be authorised. The study reports do not refer to "realistic conditions of use", that is the conditions at which the glyphosate active substance was originally authorised or proposed to be used. The situation tested by the studies could not occur since the product is not authorised in the market at the dosage used in the studies and the proposed dosage for the renewal of the approval is not based on the dosages used in the studies at hand.

5. Access to the sections protected of the study reports is not required to check the scientific risk assessment done in compliance with Regulation (EC) No 1107/2009

EFSA is aware that, according to the Court's interpretation, with a view to the objectives of Article 6(1) of the Aarhus Regulation, information enabling the public to check the assessment of the authorities is also covered by this provision. Nevertheless, it appears to EFSA that the section of the study reports concerned cannot be considered as information which relates to emissions into the environment.

In addition, not all studies relevant for the approval process are covered by the concept of the public's right to access to information which relates to emissions into the environment. The Court has not stated that simply all documents relevant for the approval are covered. It rather held that the public must have access to sufficient information (i.) to ascertain whether the emissions were correctly assessed and (ii.) must be given the opportunity reasonably to understand how the environment could be affected by those emissions.

It is EFSA's views that the summaries of the studies and the EFSA Conclusion on the peer review of the active substance glyphosate²⁴, published on EFSA's website together with the background information, are apt to achieve this objective. The Renewal Assessment Report (RAR) and background information published in

²³ According to the Court, the concept of emissions into the environment is "limited to non-hypothetical emissions, that is to say *actual* or *foreseeable* emissions from the product or substance in question under normal and realistic conditions of use", see Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting*, ECLI:EU:C:2016:890, para. 77; case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, ECLI:EU:C:2016:889, paras. 71 ff (emphasis added).

²⁴ EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302.

accordance with Article 38(1)(c) of Regulation (EC) No 178/2002²⁵ (hereinafter "EFSA's Founding Regulation") and the sectoral legislation, in particular Regulation (EU) No 1141/2010, provided the necessary information for the public to verify the assessment made by both the rapporteur Member State and EFSA and to control the Conclusion issued by the Authority on this basis. The requirements to publish certain information were made by the legislator to address the need for Union institutions, bodies or agencies of operating in a transparent fashion to EU citizens and of complying with the constitutional requirements set out in the Treaties.

Full scrutiny of EFSA's scientific assessment is possible without the requested sections since the raw data released to you contain the key elements for a complete peer review by scientific experts.

The renewal of the approval of an active substance requires that the conditions as provided for in Article 4 of PPP Regulation are met. The first assessment conducted by Germany as Rapporteur Member State and the EFSA peer review are not presented in those documents, but in the EFSA Conclusion and background documents published in 2015. The combination of the information already published with the raw data and findings provide all necessary information for a public scrutiny of the EFSA assessment.

6. Confirmatory application for access to names of the Member States experts, involved in the scientific risk assessment of the active substance glyphosate, and their declarations of conflicts of interests

Your confirmatory access application refers to the case law of the Court of Justice of the European Union (CJEU) regarding the interplay between the PAD Regulation No 1049/2001 and the Data Protection Regulation No 45/2001²⁶ referred to in paragraph 47 of the Court Judgement Case C-615/13P, cited in your letter.

As confirmed in this judgement²⁷, two cumulative conditions shall be satisfied to transfer personal data, i.e. by means of disclosing the data in the context of a public access to documents request:

- a) First, in accordance with Article 8(2) of the Data Protection Regulation, the recipient shall establish the **necessity for the transfer** of personal data. The arguments put forward in your confirmatory application to substantiate the necessity for the disclosure of the personal data at issue merely consists of a generic allegation. Concretely, you mention that EFSA "has been accused of partiality in its assessment process" because of (a) "reliance on non-published studies produced by the same actors that have an interest in getting their products approved" and (b) "the potential that the experts involved in the assessment have links with industry lobbies that can lead to potential conflicts of interests".

As concerns (a), the requirement for applicants for approval of active substances to provide study reports is laid down in Article 8(2) of the PPP Regulation. Applicants for market approval of plant protection products are thus formally obliged to provide their own studies as enclosure to the application.

As concerns (b), the viewpoint in your confirmatory application on the existence of any links with industry lobbies is purely hypothetical, which EFSA firmly denies. The

²⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1.

²⁶ 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.

²⁷ Case C-615/13 P, *ClientEarth and PAN Europe v EFSA*, EU:C:2015:489, para. 46.

73 experts that were involved in the peer review of the active substance glyphosate, in accordance with Article 12(2) of the PPP Regulation, all are civil servants employed at the public bodies of the EU Member States, the list of which has already been provided to you. They have contributed to the peer review, expressing their Member State's position, representing consolidated decisions of the national competent authorities where they are employed and for which they acted as a spokesperson on the occasion of the peer review. Being MS representatives, the national experts thus do not contribute in their personal expert capacity in the peer review and are voicing the position of their country, following a decision taken within the Member States authorities. Against this background, your allegation that the national experts may have links with industry lobbies is hereby rejected by EFSA. Being civil servants in their Member State, their independence is ensured according to the independency requirements in the statute of the national public body where they are employed and for which these national public bodies are accountable for verifying no industrial links exist.

Likewise the national experts are not involved in the peer review in their personal expertise capacity, but represent the consolidated decisions of the national competent authorities of the Member States. Besides being a purely hypothetical insinuation, the existence of any industrial links will not influence the peer review process.

For what concerns the reference made in your confirmatory access application to Case C-615/13P, *Client Earth v. EFSA*, we would like to point out that its scope differs with the case at hand: firstly, national experts involved in the peer review process are not remunerated by EFSA in the way referred to in par. 54 of this judgement, second, with reference to par. 58 cited in your confirmatory application, they are not involved "as scientists in the service of EFSA" but they contribute to the process merely representing the position of their country where they are employed as civil servants.

We would like to add that the requirements on independence and transparency laid down in Articles 37 and 38 of EFSA Founding Regulation regarding the Scientific Committee, Scientific Panels and external experts of EFSA do not extend to national experts involved in the peer review for the market authorisation of plant protection products including glyphosate in the sense of the PPP Regulation.

It follows that EFSA does not consider the allegations of a general nature regarding potential conflicts of interests of Member States representatives as founded in the present case and therefore is of the opinion that the necessity test of Article 8(2) of the Data Protection Regulation is not valid. Indeed the cases mentioned in the confirmatory application, as well as Case C-615/13P, concern external scientific experts appointed by EFSA's Management Board and not Member States representatives. Therefore these arguments are not transposable to the present situation.

b) Second, even in case the necessity for the personal data transfer would be established, quod non, it must be pointed out that compelling reasons exist to assume that the disclosure of the names and DoIs of the experts will prejudice their **legitimate interests**. In the recent past, several events and individual attacks occurred constituting a direct threat to the physical integrity and privacy of people involved as expert in EFSA's scientific work and operations.

Many newspapers articles and media at large have pointed out on specific experts involved in their personal capacity in EFSA's activities in an unfounded controversial context leading to media focus on certain individual experts.

Concrete cases have occurred in EFSA leading to consider that there is a legitimate interest to be protected, such as last year the shipment by post of a letter

containing explosive material addressed to a scientific expert Member of the Scientific Panel on Genetically Modified Organisms (GMO).

For the above reasons, EFSA considers that in the case at hand the legitimate interest of the experts from Member States might be prejudiced in the sense of Article 8(b) of the Data Protection Regulation.

Finally, with regard to your suggestion to disclose the declaration of interest – as far as in EFSA's possession – after removing the personal data from the documents, we should add such masking would render the redacted document ineffective for the intended purpose since by their very nature, DoIs mainly consist of information from which the declarant may be directly or indirectly identifiable in the sense of Article 2(a) of the Data Protection Regulation. Removing direct and obvious personal identifiers such as names are ineffective for anonymizing, since specific individuals will be easily identifiable in an indirect manner from the other information contained in the DoIs.

To add that on the occasion of previous requests for public access to documents, EFSA provided you with the list of Member States' Risk Assessment organisations involved in the peer review of active substances under the PPP Regulation. This information is also available on EFSA's website:

<http://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsmeetings>.

7. Your right to appeal

This decision of partial refusal may be challenged pursuant to Article 263 of the Treaty on the Functioning of the European Union (TFEU) by lodging an action contesting its legality before the General Court of the European Union within two months of its receipt. Further information on how to file an application can be found at <http://www.curia.europa.eu>.

In the alternative, if you believe that maladministration was committed by EFSA in dealing with the matter addressed by this decision, you have the right to make a complaint about it to the European Ombudsman pursuant to Article 228 of the TFEU and within two years of receiving EFSA's final position on the matter. Please be informed that before the Ombudsman can accept a complaint from you, it is necessary that you first raise your concerns with the Head of the Legal and Assurance Services at the European Food Safety Authority by writing an e-mail to dirk.detken@efsa.europa.eu.

The Ombudsman's online complaint form and further indications on how to file a complaint are available at: <http://www.ombudsman.europa.eu>.

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 on the scientific risk assessment process.

Yours sincerely,



Bernhard Url

Cc: D. Detken, J. Tarazona, G. de Seze, J. Ramsay (EFSA)

- Encl.: **Annex I:** Review of long-term chronic toxicity and carcinogenicity studies considered during the EU assessment, indicating the references to the published documents where the full description is available
- Annex II:** Excerpt of section B.5 of the revised RAR published in 2015, list of studies considered to be “toxicological, ecotoxicological or environmentally relevant” as per Article 63(2)(d) of the PPP Regulation