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European Parliament
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Brussels, 10 January 2017

Re: Our request for public access to documents of 15 March 2016 (Ref.: PAD 2016/034) – confirmatory application

Dear Mr. Detken,

We thank you for your letter of 7 October 2016, which we received on 11 October 2016, in which you inform us of your decision concerning our request for public access to unpublished studies on the genotoxicity and carcinogenicity of glyphosate, the herbicide. We received your letter dated 9th December and later received CDs with the documents on Tuesday 13th December. You have decided to grant us partial access to 75 unpublished studies used for the glyphosate review.

Herewith, we would like to submit a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 (hereafter referred to as "PAD Regulation"). While we welcome your decision to grant us access to the raw data and findings (aggregated in tables and figures), and while we welcome that you recognize the motivation behind our request, namely to allow for independent scrutiny of key studies used by EFSA and Member States in their assessment of glyphosate, you continue to withhold sections of the studies that in our view are crucial for an independent assessment.

1. Access to "material, experimental conditions and methods" as well as "results and discussion"

Concretely, we request that you also release the following sections of the 75 unpublished studies: "material, experimental conditions and methods" as well as "results and discussion", as these sections contain elements that are at the core of the controversy around whether or not glyphosate should be classified as a probable carcinogen. A proper independent scrutiny is not possible without these sections.

Access to these parts is necessary to be able, inter alia:
- to know about the chemical purity of the tested substance,
- to assess whether the statistical method most appropriate for the analysis of the results was established before commencing the study (included in the materials and methods section),
- to assess the origin of the animals used, as this relates to the controversial issue of historical controls (included in the materials and methods section),
- to have access to the pathology report, so as to be able to verify potentially speculative claims with regard to viral infections, to check whether the evaluation of observed tumour

incidences was done correctly, and to see whether a peer review was done by a second pathologist (pathology report included in the results section)
- to check the validity of dismissals based on "excessive toxic effects" (included in the discussion section).

For more details, please see the Annex.

You argued in your decision that these sections should not be disclosed in order to protect the economic investment of the study owners. However, we consider that any valid economic interests by the study owners would already be sufficiently protected by the non-disclosure of the appendixes and other administrative data, which you refer to in your letter of 7 October 2016 as "*the credentials that give the raw data its specific value in the context of regulatory market authorisation*".

We would like to clarify that the parts of the studies bearing the regulatory certification by dedicated laboratories and including the statement of Good Laboratory Practice (GLP) compliance should also be made available. Indeed, under Article 4(4) of Directive 2004/9/EC on GLP, "T*he 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.*"

We can accept that you will not grant access to information related to the "methods" sections insofar as it is demonstrated to be covered by Article 63(2) of Regulation (EC) No 1107/2009. However, that Article only refers to "*the method of manufacture*" (point a) and "*methods of analysis for impurities in the active substances as manufactures except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant*" (point d).

In other words, the legislator explicitly excluded methods for analysis of toxicologically relevant impurities from the methods for analysis of impurities that are normally deemed to undermine the protection of the commercial interests. By analogy, it is clear that methods for the analysis of the active substance itself, which undoubtedly is toxicologically relevant, are also not normally deemed to undermine the protection of the commercial interests.

We would like to remind you that, according to the case-law of the ECJ, the exceptions in Article 4 of the Regulation must be interpreted strictly. It is also settled in the case-law that if an institution refuses access it must explain how disclosure of the document could specifically and actually undermine the interest protected by the exception. Moreover, the risk of that interest being undermined must be reasonably foreseeable and must not be purely hypothetical. It should also be noted that the requested documents contain "environmental information" within the meaning of Regulation No 1367/2006 (the "Aarhus Regulation"). Article 6(1) of the Aarhus Regulation states that the exceptions in Article 4 must be interpreted strictly, and that the application of these exceptions must take into account the public interest served by disclosure.

Therefore, we do not agree with your claim that "*the PAD Regulation has an erga omnes effect, which means that 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 EU." On the contrary, except for the information contained in Article 63(2) of Regulation 1107/2009/EC, there is no presumption that the commercial interests of the study owners will be undermined by disclosure. EFSA must carry out an individual examination of each document and demonstrate a serious risk that is reasonably foreseeable and not purely hypothetical. EFSA has not discharged its duty in this regard, particularly in relation to the information in the "material, experimental conditions and methods" and "results and discussion" sections.

2. Access to names of the Member State experts and their declarations of conflicts of interests

The PAD Regulation contains an exception specifically to protect the "privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data". The jurisprudence developed by the European Court of Justice has established that the conditions of Regulation 45/2001 on the protection of personal data need to be fulfilled.

Article 8 of Regulation 45/2001 states that, in the absence of specific consent from the data subject, personal data shall only be transferred "if the recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subject's legitimate interests might be prejudiced."

In accordance with the jurisprudence of the European Court of Justice, summarized in paragraph 47 of Case C-615/13 P, whoever requests such a transfer must first establish that it is necessary. If it is demonstrated to be necessary, it is then for the institution concerned to determine whether there is a compelling reason to assume that that transfer might prejudice the legitimate interests of the data subject. If there is no such reason, the transfer requested must be made. If, to the contrary, EFSA determines that there is such as reason, then the various competing interests must be weighed against each other.

When it comes to the necessity of transfer, the EU Food Safety Authority has been accused of partiality in its assessment process due not only to the reliance on non-published studies produced by the same actors that have an interest in getting their products approved, but due to the potential that the experts involved in the assessment have links with industry lobbies that can lead to potential conflicts of interest.

Whilst the experts are nominated by the Member States concerned, the necessity of establishing that there is no potential for a conflict of interest is essential if citizens, EU decision-makers, elected Members of the European Parliament and NGOs and companies alike are able to be sure that the decision-making process is impartial. This was held to be the case in Case C-615/13 P Client Earth v EFSA, where the Court of Justice held that disclosure of the names of the experts who commented on an EFSA draft guidance document was necessary "*so that the impartiality of each of those experts in carrying out their tasks as scientists in the service of EFSA could be specifically ascertained*."

Indeed, as the court has already held in, inter alia, Sweden and Turco v Council (C-39/05 P and C-52/05 P), Sweden v MyTravel and Commission (C-506/08 P), Council v Access Info Europe

(C-280/11 P), and Council v in 't Veld (C-350/12 P), the transparency of the decision-making process followed by public authorities contributes to that authority acquiring greater legitimacy and leads to an increase in confidence in that authority due to the fact that the authority then becomes more accountable to citizens in a democratic system.

Transparency of the names and declarations of interest of these experts is therefore essential to specifically ascertain their independence and impartiality and so we can be sure that they are thoroughly assessing each of the studies submitted to them.

To date, you have not established reasoning as to why the legitimate interests of the data subjects might be prejudiced by the publication of their names.

Nevertheless, in the event that you decide that the names of the Member State experts should not be provided to us, we believe that the declarations of interest should still be made available (or partially available), but with the personal data removed in line with the regulation so that they are no longer identifiable "directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity".

3. **Overriding public interest with regard to the exception of Article 4(2), first indent, of the PAD Regulation concerning the "commercial interests of natural and legal person, including intellectual property"**

In case you decide to maintain your decision despite our arguments under Point 1 above, we consider that there is a clear overriding public interest in disclosure of the information on material, experimental conditions and methods, as well as results and discussion.

a) **The need to disclose the scientific evidence related to a far-reaching regulatory decision**

Glyphosate is the world's most widely used herbicide. The global use of glyphosate has increased dramatically, by a factor of 260, in the last 40 years (from 3 200 tonnes in 1974 to 825 000 tonnes in 2014)[1]. Whether or not this substance is carcinogenic is therefore of very high public interest.

Proper classification of glyphosate is of paramount importance, as a classification as carcinogenic category 1A or 1B would lead to concrete regulatory consequences under EU legislation, namely that glyphosate could no longer be approved (unless two very specific and narrow derogations apply).

According to Article 4(1) of Regulation (EC) No 1107/2009, "*An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.*

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the

1 http://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0

assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied."

Point 3.6.3. of Annex II of that Regulation sets out the following:

"*An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005*."

The EFSA conclusion on the peer review is a key basis for the Commission decision on the renewal of the approval of glyphosate. According to Article 14(2) of Regulation (EC) No 1107/2009, a renewal may be granted for up to 15 years. As indicated in the Annex, EFSA has stated publicly that "*unpublished studies that were the core basis of the peer review evaluation were not available to the IARC experts*".

We are deeply concerned that a far-reaching decision such as the renewal of the approval of the world's most widely used herbicide for 15 years should be based on unpublished studies, particularly in light of the diverging conclusion by IARC with regard to the classification of glyphosate.

Several provisions of the EU Treaties, namely Article 11 TEU and 15 TFEU, require the European Union to take decisions as openly as possible so that it contributes to strengthening the principles of democracy and respect for fundamental rights, and to ensure the protection of human health and the environment, which the EU is committed to ensure in all of its policies and activities.

The formal classification process is ongoing at the European Chemicals Agency. To ensure public accountability and credibility of this process, in addition to the peer review by EFSA, it is vital to allow for full public scrutiny of unpublished studies on carcinogenicity and genotoxicity. This requires not only the release of raw data and aggregated findings, but also access to the sections on material, experimental conditions and methods, as well as on results and discussion.

b) The application of possible risk mitigation measures and of toxicological reference values cannot compensate for a controversial classification

You argue that the public interest cannot be presumed overriding over the reasons justifying the refusal of the parts of the documents not disclosed as EFSA concluded that the high level of protection required under Regulation (EC) No 1107/2009 could be achieved through the application of available risk mitigation measures, and that the toxicological reference values proposed by EFSA would offer a sufficient margin of exposure. However, this is based on the controversial conclusion by EFSA that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008". If however glyphosate was to be classified as carcinogenic category 1A or 1B, your argument would no longer be valid, as the regulatory consequences would be triggered irrespective of possible risk mitigation measures.

c) **Assessment by JMPR not a valid contradictory assessment**

You also argue that an additional contradictory assessment of EFSA's peer review was already done by other bodies such as the Joint FAO/WHO meeting on pesticides (JMPR), implying that another assessment would not really be necessary, all the more that according to you, the JMPR "*reached a conclusion in line with the EFSA assessment on glyphosate carcinogenicity*". We shall refrain from any comments with regard to possible conflicts of interest of key members of the JMPR[2]. The JMPR adopted the conclusion "*that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet*". However, in the context of Regulation (EC) No 1107/2009, it is the classification of an active substance, safener or synergist as carcinogenic that *a priori* triggers non-approval. And classification according to Regulation (EC) No 1272/2008 is **hazard-based**, and not risk-based. In other words, a conclusion on the specific likeliness of the carcinogenic **risk** of glyphosate to humans from exposure specifically through the diet, valid or not, is not relevant for the general assessment that needs to be done pursuant to Article 4(1) and Annex II, point 3.6.3. of Regulation (EC) No 1107/2009 with regard to the classification of glyphosate.

d) **Key public actors and public institutions call for publication of the studies and/or refer to an overriding public**

To further illustrate why we consider that there is an overriding public interest, we would like to refer to:

- the letter of Commissioner Andriukaitis of 4 April 2016 to Richard Garnett, Chairman of the Glyphosate Task Force, in which he wrote the following[3]: "*This is a particularly sensitive and complex case and there is consequently a strong public request for full transparency on the studies used by EFSA for the assessment of the carcinogenicity of the substance. For this reason, I believe that the proactive publication by the Glyphosate Task Force of the full studies including the underlying raw data would be beneficiai [sic] for the society as a whole and would facilitate the ongoing discussions and the decision-making process."*

- the resolution of the European Parliament of 13 April 2016 on the "Renewal of the approval of the active substance glyphosate", which includes the following call on the Commission[4]: "*Calls on the Commission and on EFSA to disclose immediately all the scientific evidence that has been the basis for the positive classification of glyphosate and the proposed re-authorisation, given the overriding public interest in disclosure*";

- the Special Rapporteur of the Human Rights Council on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, stated the following on 14 September 2016 in the context of his mission to

2 http://www.greenpeace.org/eu-unit/en/News/2016/Industry-ties-JMPR-glyphosate/

3 Letter available on: https://ec.europa.eu/commission/2014-2019/andriukaitis/announcements/my-letter-dr-richard-p-garnett-chair-board-glyphosate-task-force-04-april-2016_en

4 Resolution available on : http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bTA%2bP8-TA-2016-0119%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

Germany[5]: "*The Special Rapporteur notes that, under international law, health and safety information about toxic chemicals should never be confidential*."

e) **Aarhus Convention and the overriding public interest where information relates to emissions into the environment**

Article 6(1) of the Aarhus Regulation lays down a legal presumption that an overriding public interest in disclosure exists where the information requested relates to emissions into the environment.

In its letter, EFSA states that "*[t]he protected sections of the studies neither contain information on emissions, discharges or other released nor information on the impact of actual emissions or discharges of glyphosate on the environment*." It also refers to case C-673/13 P which was pending at the time of the decision, and states that it "*will adapt its approach to the final ruling once available*."

The Court of Justice's judgment in this case was handed down on 23 November 2016 and it clarifies that the information requested, particularly the "material, experimental conditions and methods" as well as "results and discussion", meets the definition of "information related to emissions into the environment".

Glyphosate is clearly released to the environment when used as intended. In contrast to the interpretation adopted by EFSA in its decision, the Court has now clarified that the concept of information related to emissions into the environment "*cannot be limited to information concerning emissions actually released into the environment when the plant protection product or other active substance in question is used on plants or soil, where those emissions depend, inter alia, on the quantities of product actually used by farmers and the exact composition of the final product marketed"*[6].

The Court went on to state that *"Consequently, that concept also covers information on foreseeable emissions into the environment from the plant protection product or active substance in question, under normal or realistic conditions of use of that product or substance, namely 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*."[7]

The Court concluded that "*Although the placing on the market of a product or substance is not sufficient in general for it to be concluded that that product or substance will necessarily be released into the environment and that information concerning the product or substance related to 'emissions into the environment', the situation is different as regards a product such as a plant protection product, and the substances which that product contains, which, in the course of normal use, are intended to be released into the environment by virtue of their very function. In that case, foreseeable emissions, under normal or realistic conditions of use, from the product in question, or from the substances which that product contains, into the environment*

[5] A/HRC/33/41/Add.2

[6] Para 73

[7] Para 74

are not hypothetical and are covered by the concept of 'emissions into the environment' within the meaning of the first sentence of Article 6(1) of Regulation No 1367/2006".[8]

The requested studies are intended to evaluate the hazards posed by glyphosate emissions under normal and realistic conditions of use, including chronic and long-term exposure of the type experienced by workers, rather than waiting for the long-term effects of exposure to the emissions to manifest themselves. Animal tests often use a dose that is higher than average exposure to avoid the use of an excessive number of animals for the testing. However, the results are extrapolated to be able to draw conclusions regarding normal use over a longer term. Therefore, the studies are on foreseeable emissions; they are not hypothetical.

The Court went on to hold that "*it is also necessary to include in the concept of 'information which relates to emissions into the environment' information enabling the public to check whether the assessment of actual or foreseeable emissions, on the basis of which the competent authority authorised the product or substance in question, is correct, and the data relating to the effects of those emissions on the environment. It is apparent, in essence from recital 2 of Regulation No 1367/2006 that the purpose of access to environmental information provided by that regulation is, inter alia, to promote more effective public participation in the decision-making process, thereby increasing, on the part of the competent bodies, the accountability of decision-making and contributing to public awareness and support for the decisions taken. In order to be able to ensure that the decisions taken by the competent authorities in environmental matters are justified and in order to participate effectively in decision-making in environmental matters, the public must have access to information enabling it to ascertain whether the emissions were correctly assessed and must be given the opportunity reasonably to understand how the environment could be affected by those emissions*."[9]

The sections on material, experimental conditions and methods as well as those on results and discussion contain elements, which are essential to be able to assess whether the evaluation carried out by EFSA regarding the foreseeable emissions from the use of glyphosate and their possible effects on human health and on the environment was correct.

In these circumstances, EFSA is precluded by Article 6 of Regulation No 1367/2006 from refusing disclosure on the basis of the protection of the commercial interests of natural or legal persons.

In conclusion, we, Members of the European Parliament, request that

- on the basis of Directive 2004/9/EC on good laboratory practice, EFSA provides access to the GLP statements,
- on the basis of Regulation (EC) No 1049/2001 on public access to documents, and Regulation No 1367/2006 on the Aarhus Convention, EFSA also provides access to the sections on material, experimental conditions and methods as well as results and discussion of all 75 unpublished studies, as these are essential to allow for an independent scrutiny and do not fall under Article 4(2), first indent of the PAD Regulation, given that legitimate commercial interests of the study owners are already sufficiently protected by the non-disclosure of the information related to the introductory and administrative pages, the introduction, background and summary of

[8] Para. 75

[9] Para. 80

the studies. In case you disagree with this, we argue that there is clearly an overriding public interest in the release of those sections to allow for an independent scrutiny.

Yours sincerely,

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Bart Staes, MEP

Annex

In 2015, EFSA provided detailed answers to an Open letter by MEPs and German MPs on the EFSA peer review dated 20/10/2015[10]. In that letter, EFSA wrote:

"*Based on a comprehensive genotoxicity data package on the active substance glyphosate, and considering a weight of evidence approach on all available data, it is concluded that glyphosate is* ***unlikely*** *to be genotoxic in vivo and does* ***not*** *require hazard classification regarding mutagenicity according to the CLP Regulation. It is noted that* ***unpublished studies that were the core basis of the peer review evaluation were not available*** *to the IARC experts as reported in the IARC monograph 112 on glyphosate (IARC, 2015)*" (own emphasis added).

Most prominent amongst those pivotal unpublished studies are studies on which Greim et al. (2015) have published a review[11] as well as a supplemental material[12]. IARC did consider these studies in its monograph on glyphosate[13], but found the following: "*The Working Group was unable to evaluate these studies... because the information provided in the review article and its supplement was insufficient (e.g. information was lacking on statistical methods, choice of doses, body-weight gain, survival data, details of histopathological examination, and/or stability of dosed feed mixture).*"

This highlights the crucial importance and need to provide access to the information on material, experimental conditions and methods (which comprises statistical methods, choice of doses) as well as of the sections on results and discussion (which comprises body-weight gain, survival data, details of histopathological examination, and/or stability of dosed feed mixture). In contrast to EFSA, lack of access to this information made it impossible for IARC to consider these studies as part of their assessment on glyphosate.

The importance of statistical analysis as well as historical control data is further supported by the following statement in EFSA's conclusion on the peer review of the active substance glyphosate in relation to the diverging assessment as compared to IARC[14]: "*The assessment of the few epidemiological studies included in the IARC monograph, which were not reported in the original RAR (three out of ten cohort studies, six out of 19 case-control studies) was presented in the addendum of August 2015 to the RAR (Germany, 2015). With regard to the studies on experimental animals, three of the five mice studies used by the EU peer review and three of the nine studies in rats were* ***not*** *assessed by IARC.* ***Importantly, there is a different interpretation of the statistical analysis used to assess the carcinogenic findings in the***

10 EFSA's answers to the Open letter: *"EFSA peer review of the renewal assessment report (RAR) on glyphosate by the BfR"* by the Members of the German and the European Parliament dated 20/10/2015 and addressed to Commissioner Andriukaitis, Ref. BU/JK (2015) – out-14987881

11 Helmut Greim, David Saltmiras, Volker Mostert & Christian Strupp (2015)Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies, Critical Reviews in Toxicology, 45:3, 185-208

12 Please find the supplementary material for Greim et al. (2015) here: http://www.tandfonline.com/doi/suppl/10.3109/10408444.2014.1003423?scroll=top&

13 IARC monographs - 112

14 EFSA Journal 2015; 13(11):4302

animal studies and on the use of historical control data; the EU peer review considered relevant historical control data from the performing laboratory" (own emphasis added).

Indeed, many different scientists have raised strong concerns about the statistical analysis used by EFSA as well as the use of historical control data (see Commentary by Portier et al.[15], Report by Clausing[16]).

In a response[17] to an Open letter by Portier et al [18], the Executive Director of EFSA wrote the following: "*EFSA is of the opinion that the planning of a study before the initiation of the experimentation as established in the respective protocol – which includes the planned statistical analysis – is a key element in assessing the quality of a study; therefore deviations from the statistical analysis used by the study authors should be limited and properly justified. This is in line with OECD recommendations:* "*The central concept of this document is that the experimental design represents the strategy for answering the question of interest and that the specific statistical analyses are tactical methods used to help answer the questions. Therefore, the statistical methods most appropriate for the analysis of the data collected should be established at the time of designing the experiment and before the study starts*."

It is clear from this exchange that application of the right statistical methods is one key issue that is at the heart of the controversy. It will not be possible to resolve this without full public access to the section on material, experimental conditions and methods, which contains the statistical analysis.

To illustrate the need to have access to the results, we would like to refer to the example of the diverging information about the validity of the unpublished study by Kumar et al. 2001 (listed as Number 155 in the Annex to your letter of 31 May 2016). EFSA wrote the following in its conclusion on the peer review: "*Out of five mice studies considered, one study with Swiss albino mice showed a statistically significant increased incidence of malignant lymphomas at the top dose of 1460 mg/kg bw per day. This study was discussed at length during the first Pesticides Peer Review Experts' Meeting (PPR 125). ... The study was re-considered during the second experts' teleconference (TC 117)* ***as not acceptable due to viral infections*** *that could influence survival as well as tumour incidence – especially lymphomas*" (own emphasis added).

However, one can find the following in the proposal of the German authorities for the harmonised classification of glyphosate[19]:

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15 Portier et al. (2016) Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA), J Epidemiol Community Health doi:10.1136/jech-2015-207005

16 Peter Clausing, The Glyphosate Renewal Assessment Report; An Analysis of Gaps and Deficiencies (2015)

17 https://www.efsa.europa.eu/sites/default/files/EFSA_response_Prof_Portier.pdf

18 Portier et al., Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR, 27 November 2015

19 CLH report, Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2 Substance Name: N-(phosphonomethyl)glycine; Glyphosate (ISO) ; to be found on https://echa.europa.eu/documents/10162/9fb5d873-2034-42d9-9e53-e09e479e2612

"*During a teleconference (TC 117) on carcinogenicity of glyphosate hold by EFSA (EFSA, 2015, ASB2015-12200), it was mentioned by an U.S. EPA observer that the Kumar (2001, ASB2012-11491) study had been excluded from U.S. EPA evaluation due to the occurrence of viral infection that could influence survival as well as tumour incidences, especially those of lymphomas.* ***However, in the study report itself, there was no evidence of health deterioration due to suspected viral infection*** *and, thus, the actual basis of EPA's decision is not known*" (own emphasis added).

It would be unacceptable to dismiss positive studies based on unfounded speculations. This example highlights the need to have access to the results and discussion, so as to inter alia have access to the description by the pathologist.