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**Sent by email only**

**Subject: Your recent comments at the European Parliament debate on glyphosate**

Dear Mr Clausing

I write with regards to the debate you attended on 10<sup>th</sup> May 2017 at the European Parliament, entitled "Glyphosate – Harmless Tool or Sneaky Poison".

You made statements during this event related to EFSA's assessment of glyphosate and its appraisal of certain studies, which were inaccurate and misleading. You also misrepresented the points I presented on behalf of EFSA during the meeting I had with you on 3<sup>rd</sup> May 2017. EFSA was not present at the event and was therefore unable to challenge your claims at the time. However, I feel that it is important to set the record straight, particularly as what you said has already led to questions from the media, Members of the European Parliament, and civil society. For your information, I will be sharing this letter with those who have put questions to EFSA as a result of what you said.

Specifically, you wrongly claimed during the event that EFSA dismissed a carcinogenicity study by Kumar (2001) based solely on the testimony of Jess Rowland, a former scientist from the US-EPA who participated as an observer to an expert consultation that EFSA organized in September 2015. In fact, as I explained when we met on 3<sup>rd</sup> May, the study in question was first discussed in a meeting of Member States and EFSA experts in February 2015, alongside several other studies related to the carcinogenicity of glyphosate.

It was during the meeting in February 2015 that Member State and EFSA experts first identified weaknesses in the results presented in the Kumar (2001) study. The large majority of the experts considered it highly unlikely that glyphosate would present carcinogenic potential due to the generally recognised high background incidence of malignant lymphomas in the strain of mice used in the study and the high dose at which it occurred. The high background incidence was confirmed by a post-meeting literature search made by the Rapporteur Member State (RMS), leading the RMS to maintain its previous conclusion that glyphosate did not warrant classification for carcinogenicity. This chain of events and the nature of the experts' discussion on the Kumar (2001) study is consistently reported in the EFSA Conclusion, in the minutes of the February 2015 meeting, and in the Final Addendum of the Renewal Assessment Report (submitted in August 2015), all of which are publicly available on EFSA's website.<sup>1 2</sup>

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<sup>1</sup> See discussion on pp.1394 – 1398 of the [Pesticides Peer Review Report](#). The Kumar (2001) study is identified by the code: ASB2012-11491.

<sup>2</sup> See the [Final Addendum of the Renewal Assessment Report](#) on p.1022 (part highlighted in blue).

Studies related to the carcinogenicity of glyphosate, including the Kumar (2001) study, were discussed again in September 2015 in the expert consultation teleconference that you referred to at last week's event in the European Parliament. This teleconference was attended by Member State and EFSA experts and several observers, including Jess Rowland from the US-EPA, three observers from IARC, one observer from WHO/JMPR, and one observer from ECHA. The minutes of this teleconference are publicly available on EFSA's website.<sup>3</sup>

The observers from these organisations were invited to the expert consultation in September 2015 to present their institutions' activities, past and ongoing, in relation to the assessment of glyphosate. This was to ensure that EFSA was aware of the latest developments regarding glyphosate hazard and risk assessments being carried out by regulatory and scientific bodies around the world. The fact that there were observers at this teleconference has already been made known in public comments by EFSA.<sup>4</sup>

Furthermore, the role of observers in this teleconference was clear. They were invited to contribute to the discussions but they had no decision-making or drafting role when it came to the conclusions or recommendations of the Member State and EFSA experts in relation to the EU glyphosate assessment. The observer from the US-EPA informed participants during the teleconference about potential flaws in the Kumar (2001) study related to viral infections that could influence survival as well as tumour incidence in the mice that were tested. As indicated to you at our meeting on 3<sup>rd</sup> May, after the teleconference EFSA experts checked the Kumar (2001) study themselves and found additional indications that confirmed deficiencies in the health status of the animals, which supported the plausibility of a viral infection. In this respect, the lack of reliability in the results of this study was confirmed.

You implied in the event in the European Parliament that the presence of the observer from the US-EPA and the views he expressed with regards to the Kumar (2001) study give rise to concerns about the integrity of EFSA's glyphosate assessment. As the above shows, this allegation is not borne out by the facts. Member State and EFSA experts arrived at the conclusion that there were flaws in the Kumar (2001) study separately from, and prior to, the meeting that the US-EPA observer attended and the role of the observers was such that they were unable to influence the experts' conclusions and recommendations during the peer review process. Furthermore, as I explained to you in our meeting on 3<sup>rd</sup> May, the comments from the IARC, WHO/JMPR and US-EPA observers at the teleconference were related to their own institutions' assessments. Any potentially relevant information presented by these observers was re-checked by the European experts following the meeting, who looked at the available evidence in the studies and supporting documentation.

The raw data contained within the Kumar (2001) study has been shared with you by the four MEPs that made a Public Access for Document request on glyphosate. During our meeting on 3<sup>rd</sup> May, I indicated to you that you have all relevant information, including the raw data, to scrutinize how Member State and EFSA experts appraised the Kumar (2001) study and arrived at the conclusion that there were concerns about the reliability of its results. Furthermore, I explained EFSA's weight of evidence approach regarding studies on the carcinogenicity of glyphosate, which is also presented in detail in a recent peer-reviewed scientific publication in the Archives of Toxicology, one of the most prestigious journals in the field<sup>5</sup>.

Finally, I appreciate that you may not agree with EFSA's appraisal of the Kumar (2001)

<sup>3</sup> See discussion on pp. 1425 -1429 of the [Pesticides Peer Review Report](#)

<sup>4</sup> See page 3 of [this letter](#) from EFSA to Chris Portier, dated 13 January 2016

<sup>5</sup> <http://link.springer.com/article/10.1007/s00204-017-1962-5>

study and I respect your right to express this view. However, I find it highly unfortunate that, in doing so, you seek to sow doubt about EFSA's assessment based on unsubstantiated allegations that it was improperly influenced by the view of a single observer taking part in a single expert meeting.

I trust this clarifies EFSA's position as well as the discussions we had on this issue at our meeting on 3<sup>rd</sup> May. If you still have questions about any aspect of EFSA's assessment of glyphosate I would be happy to address them.

Yours sincerely,

Jose Tarazona

cc: Bart Staes MEP, Axel Singhofen, Pamela Bartlett Quintanilla