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European Food Safety Authority

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Brussels, 08 July 2016

Dear

Reference is made to your letter dated 17 June, in which you indicate that the European Food Safety Authority ("EFSA") has received from four Members of the European Parliament ("MEPs") a request of access to *"all studies used by EFSA to assess carcinogenicity of glyphosate and its representative formulation in their entirety, [...] all the historical control data used in that context", and to "all studies that you assessed concerning mechanisms of carcinogenicity"*. Accordingly, the EFSA consulted the Glyphosate Task Force on the accessibility of 82 studies submitted in the context of the renewal assessment of the active substance glyphosate in the framework of Regulation (EC) 1107/2009 and that have not been published in the scientific literature.

The Glyphosate Task Force on behalf of its' members would like to inform the EFSA that, for the reasons set out below, it opposes the disclosure of the 82 referred studies, including historical control and "raw data" used in their context, as well as any supporting documents in this regard.

Firstly, the Glyphosate Task Force stresses that the four MEPs requested "access" to such studies, including "raw data", without clearly stating how such terms should be understood in the context of the present request. In this respect, it should be noted that the carcinogenicity studies have been reviewed in a scientific, peer reviewed publication with a considerable amount of data which is available in an online supplement (cfr Greim H, Saltmiras D, Mostert V, Strupp C Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Crit Rev. Toxicol. 2015 Mar, 45(39):185-208. Doc 10.3109/10408444.2014.1003423;Feb 2015).

Nevertheless, access to the documents requested must be refused on the basis of the third indent of Article 4(2) of Regulation No 1049/2001, given that disclosure would undermine the protection of the European Commission's investigation, the investigation being the authorization renewal process for glyphosate. The Glyphosate Task Force is of the opinion that there is no overriding public interest justifying the disclosure of these documents and therefore aligned with the opinion issued by the EFSA in the letter dated 31 May, in which it replied that "in view of the scientific conclusions and background documents adopted and already made public by EFSA, the interest to disclose additionally in full all the studies on which EFSA based its conclusions cannot at this stage be considered to constitute per se a public interest for disclosing the unpublished studies that overrides the commercial interests of the study owners that are under investigation".

Moreover, these documents fall under the scope of the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001 which states that access shall be refused to documents received by an institution and related to a matter where the decision has not been taken. This is precisely the case here since no decision has been taken yet with respect to the renewal of glyphosate. Again, there is no overriding public interest, as provided for in Article 4(3), justifying the disclosure of the documents at issue.

In this regard, it is important to note that the EFSA analysis constitutes one step of the glyphosate renewal proceeding and should not be considered, per se, an independent investigation allowing for the disclosure of its related documents when finalized. The wording of Article 4(3) is very clear in the sense that access to a document should be denied when it “relates to a matter where the decision has not been taken by the institution”. As a matter of fact, despite the importance of the EFSA opinion, it does not have a decision-making nature, but rather serves as a supporting element to the whole proceeding, which will be finalized by a decision from the European Commission. The Glyphosate Task Force, therefore, reiterates that access to the documents requested should be denied pursuant to Article 4(3), since a final decision from the Commission ending the proceeding has not been issued so far.

In this context, documents that are part of the Commission’s file and will be used by the Commission to make a decision cannot be released without undermining the Commission’s decision-making process. In the context of heated debate which has erupted with regard to the renewal of glyphosate, the Commission needs to work calmly to reach a “well-reasoned decision”.

In addition, Article 4(2) of Regulation (EC) No 1049/2001 provides for another exception for disclosing documents when it would undermine the protection of commercial interests of a legal entity, including intellectual property. This is also the case here. Accordingly, the documents which access have been requested contain a number of sensitive information that could be misused, harming the companies inside and also outside the EU. Making the studies submitted by the members of Glyphosate Task Force in the context of the renewal assessment of the active substance glyphosate available to the public at large means also making them available to competitors who can benefit from the information to prepare their own regulatory submissions quickly and without following normal data compensation processes, rendering the investments made by our members in the study developments worthless and reducing any incentive to fund new research & development activities. The potential damages to the members of Glyphosate Task Force from such disclosure and misuse can be estimated to be more than 15 million EURO.

Finally, despite the foregoing, the Glyphosate Task Force stresses its readiness to voluntarily disclose the studies and grant access to their content through a physical reading room. Such an offer has already been made by the members of the Glyphosate Task Force with regard to 14 studies to the concerned MEPs, who declined under the argument that “only public access will be adequate to allow proper independent scientific review of those studies”. In this regard, the Glyphosate Task Force restates that the offer was made for completely open access to the reading room, and that only confidential related data would be redacted, under the terms set forth by Article 63 of Regulation (EC) 1107/2009.

In any case, the Glyphosate Task Force hereby reiterates the voluntary offer and proposes to extend access to all 82 complete study reports under the conditions described above. The Glyphosate Task Force is proceeding with the set up of such reading room and expects to have it opened within next month.

The Glyphosate Task Force would be grateful to be kept informed of the EFSA’s decision on this request.
Best regards,



EME Crop Protection Regulatory Affairs Lead