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[REDACTED]  
European Food Safety Authority  
Via Carlo Magno, 1A  
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Brussels, 14 July 2016

Dear [REDACTED],

Reference is made to your letters addressed to the Glyphosate Task force dated 17 June and 11 July, 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 in the context of the renewal assessment of the active substance glyphosate, some of them belonging to Monsanto, in the framework of Regulation (EC) 1107/2009 and that have not been published in the scientific literature.

Monsanto hereby reiterates the content of the answers submitted by the Glyphosate Task Force, and therefore also opposes the disclosure of its studies, including historical control and any supporting documents in this regard.

Firstly, 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 glyphosate's renewal approval proceeding, which is currently being analysed by the European Commission, pending a final decision. Moreover, the studies 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. It should be noted that there is no overriding public interest justifying the disclosure of these documents, neither under Article 4(2) or 4(3) of Regulation No 1049/2001.

Secondly, the first intent of 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. In the present case, a number of studies and documents which access have been requested belongs to Monsanto. In this regard, it should be noted that the studies submitted by Monsanto in the context of its renewal application, and which access have been requested by the MEPs, contain a number of sensitive and commercial relevant information that could be misused, harming the company inside and also outside the EU. Making the studies submitted by Monsanto available to the public at large means also making them available to competitors, who could easily benefit from the information provided in pursuing their own

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regulatory submissions quickly and without following normal data compensation processes. This would jeopardize Monsanto's research & development activities, putting its competitors in a favourable position without incurring the same investments.

In any case, Monsanto hereby stresses that the company did not completely deny the disclosure request, even though it has plenty grounds to do so. Together with the other members of the Glyphosate Task Force, Monsanto reiterates its willingness to voluntarily disclose its studies and grant access to their content through a physical reading room. The offer is made for completely open access, including supporting documents, and only confidential and private data would be redacted, under the terms set forth by Article 63 of Regulation (EC) 1107/2009. This approach would guarantee the protection of Monsanto's intellectual property rights and at the same time attend the request of the MEPs. Preparatory proceedings in this regards are already being finalized and the reading room should be made available within a month period for whoever is interest in accessing the studies.

Monsanto would be grateful to be kept informed of EFSA's decision on this request.

Best regards,

A large black rectangular redaction box covering the signature and name of the sender.



HELM AG

ESTABLISHED 1900

European Food Safety Authority  
Via Carlo Magno 1A  
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Italy



HAMBURG, 15.07.2016

DEPARTMENT [REDACTED]

TELEPHONE-DIRECT-NO [REDACTED]

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YOUR REFERENCE

PAD 2016/034

DATED

11 July 2016

Dear [REDACTED],

We refer to your letter of 11 July 2016 whereby you inform us that you intend to disclose our letter of reply of 1 July 2016 to four Members of the European Parliament.

As you will recall, our letter of 1 July 2016 responded to a request for access to studies submitted to EFSA for the renewal assessment of the active substance glyphosate. In order to answer this request, we attached to our letter electronic copies of the Genotoxicity Studies belonging to Helm AG (the "Studies") with confidential information redacted.

At the outset, we are surprised with the short deadline that was allocated to us for replying to your letter.

This being said, we have, in the meantime, consulted our legal advisors as part of our right of defence, and reviewed the consultations on access to documents requests within the Glyphosate Task Force (GTF) and, as a result, revisited our position set forth in our letter of 1 July 2016.

In this respect, we can only reiterate GTF's position that the request for access formulated by the Members of the European Parliament should be refused for the reasons underlined in its letter of 8 July 2016 addressed to you.

We especially emphasize, in this respect, that the Studies as well as underlying correspondence to which access is requested falls within the exception of Article 4(3), first paragraph, of Regulation 1049/2001. Indeed, they have been drawn up and received by EFSA for the purpose of carrying out the assessment of the renewal of glyphosate, for which neither an approval nor a non-approval decision has been made yet.



15.07.2016

Actually, as mentioned by the GTF in its letter of 8 July 2016, the underlying documents to which access is being requested are part of the renewal of glyphosate under AIR. That process is still ongoing and, as you know, is highly sensitive as the Commission has repeatedly been unable to adopt a final decision on such renewal despite the favourable opinion of EFSA and the Rapporteur.

It is easy to understand how access to documents at this stage could undermine that process and jeopardize the Institutions decision-making process as well as our legal position. For that reason, as already discussed between yourself and the GTF, we object to disclosure.

Moreover, as further underlined by GTF, the studies are protected (pursuant to Article 4(2) of Regulation 1049/2001) by intellectual property rights. If the studies were simply disclosed to the public, third parties could benefit from the information contained therein to prepare their own dossier submissions ahead of time and without following the normal data compensation process. This would adversely affect the commercial interests of the members of the GTF, including intellectual property rights, while rendering the investments made in the development of the studies worthless.

In other words, Helm AG - as well as all the members of the GTF - must be able to protect the studies commissioned on its chemicals as part of their company assets. If studies were routinely disclosed to the public, Helm AG and other companies engaged in research activities would no longer conduct research thereby jeopardizing their business as well as the overall system for the scientific review of plant protection products in the EU.

Therefore, we fully concur with the GTF's position set out in its letter of 8 July 2016 and object to the disclosure of the Studies on the grounds specified in this letter.

In addition, and without prejudice to the above arguments, should EFSA still consider granting access to the documents, Helm AG insists that the Studies be made available only, as part of the proposal made by the GTF in its letter of 8 July, in a reading room, with certain conditions on the management of such reading room.

We remain of course at your disposal should you have any further questions.

Yours sincerely,

**HELM AG**

