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Mr [redacted]
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By e-mail only

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8 July, 2016

Dear [redacted]

Re: Request for access to documents – PAD 2016/034

We write to you in reply to your letter of June 17 sent to the Glyphosate Task Force (GTF), in which you inform that you received a request for access to 82 toxicological studies on Glyphosate owned by members of the GTF.

Six of the studies, listed as entry 5, 25, 63, 105, 121 and 134 in Annex II to the letter (the "Studies"), have been identified as owned by Cheminova A/S.

Concerning the request for access, Cheminova formally objects to the disclosure of the entirety of the Studies and fully agrees to EFSA's position in the EFSA letter to the requestors dated May 31, 2016, in which EFSA replies: "*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EFSA based its conclusions cannot at this stage be considered to constitute per se a public interest for disclosing the unpublished studies that overrides the commercial interests of the study owners that are under investigation*".

The Studies are privately owned by Cheminova and are used for the renewal of the approval of the active substance Glyphosate under Regulation 1107/2009, which is still currently under review.

The objections to the Studies' disclosure are justified both under Article 63 of Regulation 1107/2009, as the Studies contain confidential information, as well as under Article 4(2) of Regulation 1049/2001, as disclosure of confidential data contained in and forming part of the Studies would undermine the protection of Cheminova's commercial interests.

Furthermore, as outlined below, EFSA's duty of confidentiality combined with the release of commercially sensitive information outweighs any public interest which might be purported to accrue. Consequently, the above referenced request must be rejected in its entirety.

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1. Exception to Public Access to Documents under Article 4(2) of Regulation 1049/2001

As provided by Article 4(2) of Regulation 1049/2001, the request for access to documents should be refused where the disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

As explained above, the Studies are owned by Cheminova and are protected by intellectual property rights. On that basis, all summaries, assessments and other documents included in the Studies may not be disclosed, as that would jeopardize the proper execution of Cheminova's intellectual property right and legitimate interests.

Confidentiality of the data at hand is designed to protect legitimate economic interest of Cheminova: specifically, the data represents a substantial investment in time and money for Cheminova and the findings form a part of the core data package and knowledge of relevant products, which is an essential business asset. It is a vital part of Cheminova's business interests to be able to protect all studies commissioned on its chemical products. If such studies were made easily available upon request of third parties, businesses would be reluctant to conduct research to register their substances since third parties, including competitors, would then have access to key commercial information for possible use in the EU and/or outside the EU where data protection/confidentiality rules might be more lenient and difficult to monitor and enforce.

Additionally, information about undertakings and trade secrets attracts confidentiality as commercial secrets. Commercial secrecy is given wide protection as a general principle of European Union law and is enshrined in Article 41(2) of the Charter of Fundamental Rights of the European Union. Furthermore, there are procedural safeguards to prevent serious damage from the improper disclosure of business secrets (Case C-53/85 Akzo Chemie BV and Akzo Chemie UK Ltd v Commission [1986] ECR 1965).

Furthermore, EU institutions are required to balance on the one hand the contribution which the information makes to the protection of public interest, notably disclosure for public health reasons, and on the other hand the degree of damage to commercial secrecy resulting from the disclosure of that information (see the Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04). In such an instance, the disclosure of confidential information should not be disproportionate having regard to the seriousness of the commercial damage which the disclosure may cause.

Therefore, it is clear that Article 4(2) of Regulation 1049/2001 is applicable in the current case since the disclosure of the scientific information contained in the Studies would be prejudicial to the "*commercial interests*" of Cheminova. Consequently, the request for access to documents should not be granted.

It should also be noted that, in respect of third-party documents, Article 4(4) of Regulation 1049/2001 requires institutions to consult third parties prior to disclosure. Therefore EU institutions such as EFSA have a duty to take due account of Cheminova's legitimate commercial interest in not disclosing confidential studies.

2. Confidentiality under Article 63 of Regulation 1107/2009

Article 63 of Regulation 1107/2009 contains a non-exhaustive list of information which must normally be deemed to undermine the protection of the commercial interests or the privacy and integrity of the individuals concerned, and which should therefore be treated as confidential.

Information which should normally be treated as confidential includes protected know-how relating to the scientific expertise and strategy in the compilation of the dossier the disclosure of which would undermine Cheminova's commercial interests.

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The scientific approaches and justifications relied upon by Cheminova in order to evaluate endpoints, as well as suggested and applied testing methodology, amount to proprietary scientific know-how belonging to Cheminova. Should such information be disclosed to third parties, this would reveal the know-how, registration and/or commercial strategy of Cheminova in defending its assets and undermine its competitiveness. The results of research and development undertaken by Cheminova, and its related know-how, would be adversely affected if disclosed to the public. Indeed, while Cheminova's research represents significant financial investment and time spent, that would be made worthless if it would become easily and freely accessible by third parties.

Cheminova therefore submits that the request for access to the respective documents should not be granted since it contains confidential information which is the property of Cheminova.

3. Alternative: Closed Data Room

Without prejudice to the above arguments, should EFSA still consider granting access to the Studies or any parts thereof to the requesting third party, Cheminova would insist on making the Studies only available to the third party in a closed physical data room, without any possibility to make copies, reproduction or communication of data and information contained in or as part of the Studies.

This would allow the third party requestor to view the Studies in their entirety with only information identified as confidential in Article 63 of Regulation 1107/2009 and privacy related data redacted, without the possibility of referring to or using the Studies for its own ends, while limiting the detrimental effects of the disclosure of the Studies for Cheminova. Prior to the third party viewing the Studies, Cheminova would request an opportunity to sanitise the Studies based on the above mentioned principles.

We thank you for your consideration of the points raised in this letter and for an urgent reply, and will await your reply to this letter prior to undertaking further actions with respect to the Studies.

Should EFSA, following and taking consideration of this letter, continue to wish to receive sanitised copies of the Studies, we note from the correspondence between the requestors and EFSA, that EFSA, by estimating that a total of 1600 hours would be needed to consider confidentiality claims for the 82 studies, is very well aware that sanitisation of this type of studies is a very time consuming task, and we request that a reasonable period of time is provided to conduct such sanitisation.

We further note that the EFSA letter refers to the "Studies" which we understand are the actual study reports, including any annexes. The access via a closed data room as mentioned under item 3 relates to access to the study reports. It does not relate to raw data in the form of laboratory journals, slides with biological material and similar records, which are original information stored as raw data under strict GLP conditions.

Yours sincerely,
Cheminova A/S

[redacted]
Regulatory Affairs Manager