EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/AS/np (2017) 1094318

By registered mail with acknowledgment of receipt

Mr Vincent Harmsen
c/o Simon de Bergeyck
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1150 Brussels
Belgium

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Dear Mr Harmsen,

Subject: Your applications for access to documents – Ref GestDem Nos 2016/7243 and 2017/40

We refer to your emails dated 22/12/2016 and 03/01/2017, registered on 23/12/2016 and 03/01/2017 under the above mentioned reference numbers, by which you request access to documents on the basis of Regulation (EC) No 1049/2001[1].

In the letter to you registered as Ares(2017)354636, DG SANTE proposed to you to release, at regular intervals, batches of documents cleared for release and to give you a reasoned opinion explaining why some documents cannot be entirely or partially disclosed. You agreed to our proposal for a fair solution on 17 January and this reply concerns the second batch of documents.

1. Scope of your request

The scope of the second batch of documents concerns the part of your request in which you asked access to:

all correspondence (including emails), agendas, minutes of meetings or any other reports of such meetings where the active substance glyphosate in relation to the re-approval of the active substance was discussed/mentioned/referred to by officials of DG SANTE and representatives/officials of the following organizations and services of the European Commission (between 28 May 2016 and 17 January 2017):

ECPA, Cefic, CropLife America, ACC, AmCham, Bayer, Monsanto, BASF, Syngenta, Dow Chemicals, DuPont, BusinessEurope, CopaCogeca, Glyphosate Task Force, Hume Brophy, Fleishman-Hillard, Interel European Affairs, EPPA SA, European Forum for

[1] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Renewable Energy Sources, FTI Consulting Belgium, Grayling, Kreab, Weber Shandwick, Acumen public affairs, Steptoe & Johnson LLP, Dr. Knoell Consult, or any consultancy representing the above mentioned parties

2. Identification and assessment of the concerned documents

We have identified 72 documents falling under the scope of this part of your request.

Since some of the requested documents originate from third parties, the originators of the documents have been consulted in accordance with Regulation (EC) No 1049/2001, in order to assess whether an exception to the right of access to documents is applicable.

Having examined the documents and considered the opinions of these third parties, we have come to the conclusion that:

i. partial access can be granted to the documents that are indicated with "Partial" in the list of documents;

ii. the document indicated with "No" in the list of documents is protected in its entirety.

You will find in annex to this letter the documents that are indicated with "Partial" as well as a table with the list of documents containing the result of the assessment carried out on their content on the basis of Regulation (EC) No 1049/2001.

You may re-use Commission documents free of charge for non-commercial and commercial purposes provided that the source is acknowledged, that you do not distort the original meaning or message of the documents. Documents originating from third parties cannot be re-used without the agreement of the originators.

3. Reasons for refusal

Document 1

The document is a letter from Barclay Crop Protection regarding the renewal of the active substance glyphosate. The document contains commercially sensitive business information relating to the market share and turnover of the company and its disclosure would provide to competitors information which may cause damages to the company.

We have considered and decided that partial access can be granted to the document. The exception laid down in Article 4(2), first indent, of Regulation (EC) No 1049/2001 apples to the redacted parts of document 1.

Document 4, 32, 48, 49, 50 and 52

The documents are letters sent by the Commission to the companies that submitted dossiers for the inclusion of glyphosate in Annex I to Directive 91/414/EEC[2] regarding the review of the existing approval of glyphosate. The documents contain information relating to the harmonised classification as regards carcinogenicity of glyphosate which was one of the key elements for which it was decided to postpone the decision on renewal and extend the current approval period. The decision-making process is still ongoing. The opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate is not yet finalised and a decision on the renewal of glyphosate has not yet been taken by the Commission following a vote in the Standing

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (Directive 91/414/EEC).

Committee for Animals, Plants, Food and Feed. Providing full access to the documents at this stage would undermine the decision-making process of the Commission, as it would lead the Commission to have to defend preliminary assertions expressed in the ongoing decision-making process. This would effectively deprive the Commission from having frank internal discussions in order to explore all possible options in preparation of a decision free from external pressure.

We have considered and decided that partial access can be granted to the documents. The exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to the redacted parts of the documents 4, 32, 48, 49, 50 and 52.

Document 21

The document is the response of Barclay Crop Protection to the Commission's letter regarding the review of the existing approval of glyphosate. The document was required and received by the Commission for the purpose of carrying out the assessment of the renewal of the active substance glyphosate. The document contains commercially sensitive business information relating to the market share and turnover of the company and its disclosure may cause damages to the company. The document also contains information related to the harmonised classification as regards carcinogenicity of glyphosate which was one of the key elements for which it was decided to postpone the decision on renewal and extend the current approval period. The decision-making process is still ongoing. The opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate has not yet been finalised and a decision on the renewal of glyphosate has not yet been taken by the Commission following a vote in the Standing Committee for Animals, Plants, Food and Feed. Providing full access to the document at this stage would undermine the decision-making process of the Commission, as it would lead the Commission to have to defend preliminary assertions expressed in the ongoing decision-making process. This would effectively deprive the Commission from having frank internal discussions in order to explore all possible options in preparation of a decision free from external pressure.

We have considered and decided that partial access can be granted to the document. The exceptions laid down in Article 4(2), first indent, as well as Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 apply to the redacted parts of document 21.

Document 23, 24, 28, 29, 35 and 38

The documents are the responses of ADAMA, Cheminova, Excel Crop Care, Monsanto and Syngenta to the Commission's letter regarding the review of the existing approval of glyphosate. The documents were required and received by the Commission for the purpose of carrying out the assessment of the renewal of the active substance glyphosate. The documents contain information related to the harmonised classification as regards carcinogenicity of glyphosate which was one of the key elements for which it was decided to postpone the decision on renewal and extend the current approval period. The decision-making process is still ongoing. The opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate has not yet been finalised and a decision on the renewal of glyphosate has not yet been taken by the Commission following a vote in the Standing Committee for Animals, Plants, Food and Feed. Providing full access to the documents at this stage would undermine the decision-making process of the Commission, as it would lead the Commission to have to defend preliminary assertions expressed in the ongoing decision-making process. This would effectively deprive the Commission from having frank, internal discussions in order to explore all possible options in preparation of a decision free from external pressure.

We have considered and decided that partial access can be granted to the documents. The exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to the redacted parts of document 23, 24, 28, 29, 35 and 38.

Document 56

Document 56 contains the minutes of a meeting between Monsanto and DG SANTE officials. The document contains information related to the ongoing work on the harmonised classification of glyphosate, which was one of the key elements for which it was decided to postpone the decision on renewal and extend the current approval period. The decision-making process is still ongoing. The opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate has not yet been finalised and a decision on the renewal of glyphosate has not yet been taken in the Standing Committee for Animals, Plants, Food and Feed. Providing full access to the document at this stage would undermine the decision-making process of the Commission, as it would lead the Commission to have to defend preliminary assertions expressed in the ongoing decision-making process. This would effectively deprive the Commission from having frank, internal discussions in order to explore all possible options in preparation of a decision free from external pressure.

In addition to pesticides, the authorisation of genetically modified organisms (GMO) was discussed at the said meeting, which is unrelated to the renewal of glyphosate. That part of the discussion is therefore redacted as it is considered to fall outside the scope of your request.

We have considered and decided that partial access can be granted to the document. The exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to the redacted parts of document 56.

Document 66

The documents contain annexes sent to the Commission in response to the EFSA's request for data on the potential endocrine activity of glyphosate. The documents relate to the assessment of the renewal of the active substance glyphosate for which the decision-making process is still ongoing and concern the properties of the active substance. The disclosure of the documents would undermine the protection of the decision-making process of the Commission (Article 4(3), first subparagraph), as it would lead the Commission to have to defend preliminary assertions expressed in the ongoing decision-making process. This would effectively deprive the Commission from having frank internal discussions in order to explore all possible options in preparation of a decision free from external pressure. The annexes also contain confidential business information as well as proprietary information, and their disclosure would undermine the commercial interest of Monsanto as well as the Glyphosate Task Force (Article 4(2), first indent).

The exceptions laid down in Article 4(2), first indent, and Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 apply to the said annexes. We have considered whether partial access could be granted. However, the said annexes are entirely covered by the above mentioned exceptions.

4. Overriding public interest

The exceptions to the right of access provided for in Article 4(2) and 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested documents. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC)

No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001. The public interest in this case is rather to protect the commercial interests of the legal persons concerned and the Commission's decision-making process.

5. Protection of personal data

Documents 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 59, 60, 61, 62, 63, 64, 65, 67, 68, 69, 70, 71 and 72, contain personal data, such as the names, signatures and telephone numbers of staff of the Commission, Albaugh, Barclay, Brokden, Cheminova, Copa-Cogeca, Dow AgroSciences, ECPA, Excel Crop Care, Glyphosate Task Force, Hume Brophy, Nufarm, Monsanto, SFP, Sinon, Syngenta and UPL. Pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access to a document has to be refused if its disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001[3].

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable.[4] According to Article 8(b) of this Regulation, personal data shall only be transferred to recipients if they establish the necessity of having the data transferred to them and if there is no reason to assume that the legitimate rights of the persons concerned might be prejudiced.

We consider that, with the information available, the necessity of disclosing the aforementioned personal data to you has not been established and that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, partial access is granted to the requested document, expunged of personal data.

6. Means of redress

Should you wish this position to be reconsidered, you should present in writing, within fifteen working days from receipt of this letter, a confirmatory application to the Commission's Secretary-General at the address below.

The Secretary-General will inform you of the result of such review within 15 working days from the date of registration of your request. You will either be given access to the document or your request will be rejected, in which case you will be informed of what further action is open to you.

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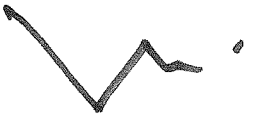
[3] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

[4] Judgment of the Court of Justice of the EU of 29 June 2010 in case C-28/08 P, Commission/The Bavarian Lager Co. Ltd, ECR 2010 I-06055.

All correspondence should be sent to the following address:

European Commission
Secretary-General
Transparency unit SG-B-4
BERL 5/282
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,



Xavier Prats Monné