

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels, SANTE/E4/AS/gb(2017)

By registered mail with acknowledgment of receipt Mr Vincent Harmsen c/o Simon de Bergeyck Rue au Bois 216 1150 Brussels Belgium

Advance copy by e-mail: ask+request-3671-ecd8e850@asktheeu.org

Dear Mr Harmsen,

Subject: Your application for access to documents – Ref GestDem No 2016/7243

We refer to your email dated 22/12/2016 registered on 23/12/2016 under the above mentioned reference number, by which you request access to documents on the basis of Regulation (EC) No 1049/2001¹.

In the letter to you registered as Ares(2017)192850, 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 2017 and this reply concerns the third and fourth batch of documents, as was explained to you in our letter registered as Ares(2017)354636.

1. Scope of your request

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

- all internal documents, correspondence (including emails), agendas, phone logs, 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, or where the ongoing work of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) on the active substance glyphosate in relation to the re-approval of the active substance, was discussed/mentioned/referred to by officials of DG SANTE
- 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/foreign

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

governments/DGs and services of the European Commission: US government, Canadian government, Brazilian government, DG TRADE, DG GROWTH, DG AGRI, DG ENV, EFSA, EEAS, Secretariat-General

Between 1 March 2015 and 17 January 2017.

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. 8 documents (Nos 2, 7, 23, 27, 32, 63, 64 and 70) have already been released to you in previous requests or in previous batches of this access to document request, these are indicated in the list of documents;
- ii. full access can be granted to 5 documents, 4 of which are publicly available and indicated with "Public" in the list of documents (Nos 3, 5, 6 and 68), and 1 of which full access is granted and indicated with "Yes" in the list of documents (No. 66);
- iii. partial access can be granted to 48 documents that are indicated with "Partial" in the list of documents (Nos 1, 4, 8-22, 24, 26, 28-31, 33, 34, 36-38, 41-44, 46, 46.1, 49, 50, 52-55, 57-62 and 67);
- iv. 11 documents indicated with "No" in the list of documents are protected in their entirety (Nos 25, 35, 39, 40, 45, 47, 48, 51, 56, 65 and 69).

You will find in annex to this letter all documents that are indicated with "Yes" and "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.

The four documents already publicly available can be found online:

Document 3: http://ec.europa.eu/dgs/health_food-

safety/advisory groups action platforms/working groups 2015 en.htm

Document 5 and 6: http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?11

Document 68: http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?6

3. Out of scope

Documents 12, 14, 15, 16, 17, 18, 19, 20, 22, 26, 28, 29, 30, 35, 36, 37, 44, 45, 47, 48, 50, 54, 55, 58, 59, 60 and 62 are minutes of internal meetings and contain information on other topics that are unrelated to the re-approval of glyphosate. As the documents identified are numerous and the volume of the information out of scope of this request is considerable, we have created a new document listing only the parts that fall within the scope of this access to documents request. This is done purely to reduce the workload to redact a large number of documents where most of the information is out of scope. This document, *EXTRACTS from meetings GestDem 2016-7243* is annexed to this letter.

Also, documents 11, 13, 21, 21.1, 24, 33, 34, 38, 41, 42, 43, 46.1, 49 and 52 contain information on other topics that are unrelated to the re-approval of glyphosate. These parts of the documents have been redacted as they concern information that falls outside the scope of the request.

Document 24 is a mission report from the Commissioner's visit to IARC in Lyon. The email has two attachments, both of which are out of scope of this request as the content is unrelated to the re-approval of glyphosate. These two documents are neither included in the list of documents, nor are they annexed to this letter.

4. Reasons for refusal

Documents with reference to the positions of Member States

The decision on the re-approval of glyphosate was postponed in order to wait for the opinion of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA). This opinion is expected to be published in the coming months (before summer 2017) whereby the Commission has six months to take a decision on the re approval of the active substance. The decision-making process is therefore currently fully open and ongoing.

Documents containing information regarding the opinions and positions of specific Member States regarding the re-approval of glyphosate are protected. This information has been gathered in the framework of the Standing Committees, where the active substance glyphosate has been discussed on numerous occasions. More specifically, the documents protected for this reason are:

- · in their entirety, documents numbered 39, 40 and 51,
- the entire extracts of documents numbered 35, 45, 47 and 48,
- the redacted parts of the extracts of documents numbered 37 and 50,
- the redacted parts of documents numbered 38 and 43.

The Standard Rules of Procedures for the Standing Committees², which the Commission adopted pursuant to Article 9 of Regulation (EC) No 182/2001³, explicitly exclude the positions of individual Member States from public access. In fact, Articles 10(2) and 13(2) of the Standard Rules of Procedure affirm, respectively, that summary records of the meetings shall not mention the position of individual Member States in the committee's discussions and that the committee's discussions shall be confidential.

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OJ C 206, 12.7.2011, p. 11.

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13.

It follows that the Commission cannot grant public access under Regulation (EC) No 1049/2001⁴ to documents containing references to the individual Member States that expressed opinion in the framework of committee meetings, as this would result in the above-mentioned confidentiality requirement being deprived of its meaningful effect.

In its Corporate Europe Observatory judgment⁵, the General Court confirmed that minutes circulated to participants in the framework of a meeting which was not open to the public, are to be considered as "internal documents" within the meaning of Article 4(3) of Regulation (EC) No 1049/2001 and deserve protection on that basis. The same reasoning applies, a fortiori, to the positions of Member States expressed in the framework of Standing Committees' meetings and consequently referred to in documents such as minutes of other meetings.

In fact, the Member States and the Commission must be free to explore all possible options in preparation of a decision within Standing Committees free from external pressure. Public disclosure of the references to individual Member States would prevent Member States from frankly expressing their views in the framework of Standing Committees meetings and thus seriously undermining the possibility of the Commission to explore all possible options in preparation of a decision and impairing the quality of the decision-making process. Therefore, public access to references to individual Member States would seriously undermine the ongoing decision-making process on endocrine disruptors.

We have considered whether partial access can be granted to the documents and have come to the conclusion that the exception laid down in Article 4(3), first paragraph, of Regulation (EC) No 1049/2001 applies to documents 39, 40 and 51 in their entirety as well as to the entire extracts of documents 35, 45, 47 and 48. However, partial access can be granted to documents 38 and 43, and to the extracts of document 37 and 50, the exception laid down in Article 4(3), first paragraph, of Regulation (EC) No 1049/2001 applies to the redacted parts of the documents and extracts.

Draft regulations on the re-approval of glyphosate

Documents numbered 25 and 56 are draft Commission Implementing Regulations and relate to a decision which has not yet been taken by the Commission. Having examined these documents, we regret to inform you that access cannot be granted. Document 25 was submitted for discussion at the meeting of the Standing Committee on Plants, Animals, Food and Feed – Section "Plant Protection Products – Legislation", held on 28 and 29 January 2016, and document 56 was submitted for discussion at the Standing Committee, held on 18 and 19 May 2016; no decision on their final content has been taken to date. Disclosure of these documents at this point in time would undermine the protection of the decision-making process of the Commission, as it would reveal preliminary views and policy options which are currently under consideration. The Commission's services must be free to explore all possible options in preparation of a decision free from external pressure. We have considered whether partial access can be granted to the documents. However, the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to the two documents in their entirety.

Judgment of the General Court of 7 June 2013 in case T-93/11, Stichting Corporate Europe Observatory v European Commission, paras 32-33.

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43.

Document 65

Document 65 is a back-to-office note from the ECHA-RAC meeting on 7 December 2016 where glyphosate was discussed for the first time. 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 of the active substance. The opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate has not yet been finalised, but is expected in the coming months. Providing full access to the document at this stage would undermine the decision-making process of the Commission, as it would lead the Commission and the ECHA to have to defend preliminary assertions expressed in the early discussions of the Committee. The dissemination of preliminary, potentially obsolete views would risk confusing the public and stakeholders rather than providing clarity on the issue in question. We have considered whether partial access can be granted to the document. However, the exception laid down in Article 4(3), first paragraph, of Regulation (EC) No 1049/2001 applies to the document in its entirety.

Document 69

Document 69 is a note to the Head of Cabinet of Commissioner Andriukaitis and contains the state of play on the active substance glyphosate. The document is outlining the internal reflections on the file and potential policy options and way forward depending on the opinion of the Committee for Risk Assessment of the ECHA on the classification of glyphosate, as well as the outcome of the EFSA assessments of the impact of glyphosate residues in feed on animal health and endocrine disruptive properties of glyphosate. Releasing the document, before a final decision on the re approval of the active substance has been taken, disclosing the internal reflections of the Commission would seriously undermine the Commission's decision-making process with regard to the re-approval of glyphosate. It would expose the current preparatory actions and internal assessments to undue external pressure and disseminate preliminary, internal conclusions. The risk of such external pressure is real and non-hypothetical given the specific and fundamental interest of stakeholders such as non-governmental organisations.

Therefore, following premature public release of the document, the Commission would no longer be free to explore all possible options in this sensitive area free from external pressure. It would prejudice the institution's margin of manoeuvre and severely reduce its capacity to contribute to reaching compromises with Member States. The Commission must be free to inform its services about ongoing sensitive files in internal briefings, and furthermore be free to discuss and outline its internal reflections, conclusion and preparatory action. Releasing the information at this point in time would effectively deprive the Commission from having frank internal information exchange in order to explore all possible options in preparation of a decision free from external pressure. It would also lead the Commission to have to defend preliminary views expressed. Furthermore, the same reasoning as for the back-to-office note from the RAC meeting applies, that the dissemination of preliminary, potentially obsolete positions would risk confusing the public and stakeholders rather than providing clarity on the issue in question. We have considered whether partial access can be granted to the document. However, the exception laid down in Article 4(3), first paragraph, of Regulation (EC) No 1049/2001 applies to the document in its entirety.

5. Overriding public interest

The exceptions to the right of access provided for in Article 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.

6. Protection of personal data

Documents 1, 4, 8, 9, 10, 11, 13, 14, 21, 21.1, 24, 31, 33, 34, 36, 38, 41, 42, 43, 46, 46.1, 49, 52, 53, 57, 61 and 67 contain personal data, such as the names, email-addresses and telephone numbers of non-managerial staff of the Commission. 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 45/2001⁶.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable. 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 documents, expunged of personal data.

7. 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.

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.

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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).

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