Dear Mr Harmsen,

Subject: Your application for access to documents – Ref GestDem No 2017/4461

We refer to your e-mail dated 31 July 2017 in which you make a request for access to documents, registered the same date under the reference number mentioned above. The time limit in accordance with Article 7(3) of Regulation (EC) No 1049/2001 regarding public access to documents expires on 12 September 2017 (see Ares(2017)3850183 registered 1st August 2017).

1. Scope of your request

In your request, you asked access on the basis of Regulation (EC) No 1049/2001 for:

"All communications (including emails, letters, minutes of meetings and any other reports of such meetings) and all possible documents (including working documents and draft documents) in relation to the following chapters of the impact assessment related to defining criteria for identifying endocrine disruptors (available online here: http://bit.ly/2vhxylx):

-ANNEX 9:
  1. ENDOCRINE DISRUPTORS AND HORMONE RELATED DISEASES - EVIDENCE
  1.2. Epidemiological and laboratory data on a link between exposure to EDs and "hormone related diseases"
  1.2.1. Interpretation of epidemiological data
  1.2.3. Toxicological principles (e.g. existence of safety thresholds, potency of chemicals, shapes of dose-response curve, low dose effects)
-ANNEX 11:
  3.1. Evidence on possible association between ED exposure and wildlife population declines".

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
You further request information on discussions/mention/reference to twenty scientific publications cited in these Annexes of the impact assessment report:

"in relation to this request are -- although this request is not limited to -- all possible communications and/or documents (as specified above) where the following publications are discussed/mentioned/referred to in an explicit or implicit way:...

... LIST OF TWENTY SCIENTIFIC PUBLICATIONS CITED IN THE MENTIONED ANNEXES...

You further clarify that:

"'In relation to' in this request is to be interpreted in the broadest sense possible, meaning all communications and documents (as specified above) that hold any information whatsoever that sheds light on the process that led to the creation of the chapters mentioned: selection of sources, quoting and paraphrasing from sources, analyzing information, drafting texts, drawing conclusions, etc.".

2. Identification of the concerned documents

We have identified 73 documents as potentially falling under the scope of your request (see table 1 attached to this reply).

Please note that none of these documents are as such specifically or exclusively related to Annex 9 and Annex 11 of the Impact Assessment on defining criteria for identifying endocrine disrupters or to the list of twenty scientific publications mentioned in your request. In fact, no such documents have been identified. However, we have interpreted your request in the broadest sense possible and we have identified all documents related to the impact assessment as a whole.

3. Assessment of the documents

Having examined the documents, we have come to the conclusion that:

i. full access can be granted to the documents that are indicated with "Yes" and "Public" in table 1;

ii. partial access can be granted to the documents that are indicated with "Partial" in table 1.

Please find attached the documents that are indicated with "Yes", "Public" and "Partial" as well as table 1 containing the assessment carried out on their content on the basis of Regulation (EC) No 1049/2001.

You may reuse 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.
4. Reasons for refusal

For the documents listed with "No" in table 1, the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies.

In these cases, the decision-making process is still ongoing. This holds for the documents concerning the scientific criteria for identifying endocrine disruptors for which the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 is indicated in table 1 as reason for refusal. The criteria are currently being scrutinized by the European Parliament and the Council, and the possibility that the Commission might need in future to discuss again the criteria cannot be excluded at this stage.

Disclosure of these documents would undermine the protection of the decision-making process of the Commission, as it would reveal preliminary views and policy options which might be considered. The Commission services must be free to explore all possible options before finalisation of a decision without this process being influenced.

Therefore, the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to these documents.

Partial access can be granted to the documents 12, 13 and 34.

We have considered whether partial access could also be granted to the documents 15, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 62, 63, 64 and 65. However, these documents are fully protected by the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001.

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.

6. Protection of personal data

Some of the documents to which you have requested access contain personal data, such as the names of associations, organizations, institutions staff or Commission's non-managerial staff, and/or biometric data, such as hand-written signatures.

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 Community legislation regarding the protection of personal data. The applicable legislation in this field is 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.\(^1\)

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable.\(^2\)\(^3\)

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/or that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, we are disclosing the documents requested expunged from this personal data.

7. Means of redress

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at 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

Annex:

— Table (list of documents)

— CD-ROM with documents that can be (partially) disclosed


\(^3\) 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.