



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E3/SH/aj/ddg2.e.3(2016) 2598816

***By registered letter with
acknowledgement of receipt***

Advance copy by e-mail to:
ask+request-2689-221ed3b8
@asktheeu.org

Dear Mr Harmsen,

Subject: Your application for access to documents – Reference GestDem No 2016/1300

We refer to your e-mail dated 14 March 2016 registered on 15 March 2016 under the above mentioned reference number, in which you request access to:

“all correspondence (including emails), agendas, (working) documents, minutes of meetings and any other reports of such meetings related to the Inter-Service Steering Group for the impact assessment concerning measures on animal cloning for food production in the EU (between December 2011 and January 2014)”.

On 28 April 2016¹, we had already provided you with 20 documents. The remaining 52 documents covered by your request are listed in Annex 0 to this letter. The numbering of these documents in that Annex continues the numbering initiated in our previous reply.

Two documents in this list originate from the Commission’s Legal Service (number 25 and 25.1), who will reply to you separately concerning the access to these documents, under your request registered under the reference GestDem 2016/2286.

After having examined these documents under the provisions of Regulation (EC) No 1049/2001², we can grant full access to 3 of these documents (documents No 7.1, 12.1 and 13.2) and partial access to 23 of them³. The disclosure of the 24 other documents⁴ must be refused. The grounds for partial access and refusal of access are exposed below.

Mr Vincent Harmsen
Pieter Schroonsstraat 58
1830 Machelen
Belgium

¹ Our reference Ares(2016)2022277.

² 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, 31.5.2001, p. 43.

³ Documents No 7, 8, 9, 10, 12, 13, 13.1, 14, 14.1, 15, 16, 17, 18, 19, 19.1, 20, 20.1, 21, 22, 23, 26, 28 and 29.

⁴ Documents No 7.2, 9.1, 10.1, 11, 12.2, 12.3, 13.3, 15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.7, 17.1, 23.1, 23.2, 24, 27, 27.1, 27.2, 28.1, 28.2 and 28.3.

1. Protection of personal data

In all the documents that are partially disclosed, personal data have been removed. 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 Union 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*⁵.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable⁶. 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 these documents expunged from these personal data.

2. Protection of the Commission's decision-making process

Documents No 8, 16, 18, 21, 22, 26 and 29 concern reports of DG SANTE staff from the Inter-service steering group (ISSG) meetings and document No 20.1 concerns a presentation given by DG SANTE staff in the ISSG. Therefore, the disclosure of parts of these documents in which policy options are discussed would undermine the protection of the decision-making process of the Commission. This exception is covered by Article 4(3), first and second subparagraph, of Regulation (EC) No 1049/2001. Therefore, these documents are partially expunged on the basis of this exception.

The exception of the protection of the decision-making process of the Commission also applies to the documents the disclosure of which is entirely refused, with the exception of document No 12.3.

In respect of documents number 8, 16, 18, 20.1, 21, 22, 26 and 29, it has to be recalled that although the Commission's proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes⁷ and a proposal on the placing on the market of food from animal clones,⁸ accompanied by an impact assessment,⁹ were adopted on 18 December 2013, the decision-making process is still ongoing and the Commission is involved in the ordinary legislative procedure regarding the adoption of these proposals. The Commission must indeed defend the proposals at working level at the

⁵ Official Journal L 8 of 12.1.2001, p. 1.

⁶ 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-6055.

⁷ Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes - COM(2013)0892.

⁸ Proposal for a Council Directive on the placing on the market of food from animal clones - COM(2013)0893.

⁹ SWD(2013) 519 final.

Council (Council Working Parties) and in the relevant Committees of the European Parliament.

Moreover, the Commission has to formally issue an opinion in first reading and second reading on the amendments of the co-legislators to the proposals (Article 294(6), (7)(c) of the Treaty on the Functioning of the European Union ('TFEU')). Where the Commission delivers a negative opinion on the Council's amendments, the latter has to adopt its amendments unanimously (Article 294(9) TFEU). Moreover, the Commission can alter its proposal any time during the legislative procedure, as long as the Council has not acted (Article 293(2) TFEU).

Disclosing the documents or parts of documents concerned at this stage would seriously undermine the Commission's decision-making process as it would reveal views and policy options which are currently under consideration in the legislative debate. The Commission's services must be free to explore all possible options in preparation of a decision free from external pressure, as long as the decision-making process is still ongoing.

The Commission therefore considers that Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 is applicable¹⁰.

If the decision-making process were considered to be closed following the adoption of the Commission's proposals – quod non – I consider that the refused documents and parts of documents would nevertheless be covered by the exception provided for in Article 4(3) of Regulation (EC) No 1049/2001, second subparagraph, for the same reasons as explained above.¹¹ Indeed, disclosing those documents or parts of documents, reflecting opinions for internal use as part of preliminary deliberations, would seriously harm further Commission decision-making processes as regards the legislation on cloning.

3. Protection of the commercial interests of a legal person

The document No 12.3 titled "*Impact in the EU and third countries of measures on animal cloning for food production in the EU*" is the proposal from ICF GHK to DG SANCO in which ICF GHK explains its methodology, approach and planning on how to carry out the requested study.

Having examined this document requested under the provisions of Regulation (EC) No 1049/2001, I came to the conclusion that its disclosure would undermine the protection of the commercial interest of ICF GHK. It would notably give information on the resources and specific know-how of this company. Therefore, the exception laid down in Article 4(2), first indent, of Regulation (EC) No 1049/2001 applies to this document.¹²

¹⁰ Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 reads: "Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

¹¹ Article 4(3), second subparagraph, of Regulation (EC) No 1049/2001 reads: "Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

¹² Article 4(2), first indent, of Regulation (EC) No 1049/2001 reads: "The institutions shall refuse access to a document where disclosure would undermine the protection of: — commercial interests of a natural or legal person, including intellectual property,"

4. Final considerations

The exceptions regarding the right of access to documents laid down in Article 4, paragraphs 2 and 3 of Regulation (EC) No 1049/2001 (cf. sections 2 and 3 above) apply unless there is an overriding public interest in disclosure of these documents. While it is acknowledged that the issue of cloning raises considerable interest in the public and in the media, this does not outweigh the harm to the Commission's decision making process if all internal considerations of policy approaches on a file that is in the decision-making process were publicly released.

Concerning the 24 documents access to which is entirely refused, we have considered whether access could be granted to parts of these documents. However, it appears that they are entirely covered by the aforementioned exceptions.

Please note that one of the documents disclosed (number 14.1) emanates from a third party. It is disclosed for information only and cannot be re-used without the agreement of the originator, who holds a copyright on it. It does not reflect the position of the Commission and cannot be quoted as such.

You may reuse the Commission documents fully or partially disclosed 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 document. Please note that the Commission does not assume liability stemming from the reuse.

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 e-mail to: sg-acc-doc@ec.europa.eu

Yours sincerely,

A handwritten signature in black ink, consisting of a series of connected, somewhat jagged lines that form a stylized representation of the name 'Xavier Prats Monné'.

Xavier Prats Monné