



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels,
SANTE/AB

***By registered mail with
acknowledgment of receipt:***

Ms Aisha Down
Level 5, Calea Victoriei 21
Bucharest
Romania

Advance copy by email:
[ask+request-7264-
d22b6c08@asktheeu.org](mailto:ask+request-7264-d22b6c08@asktheeu.org)

Dear Ms Down,

Subject: Your application for access to documents – Ref GestDem 2019/5140

We refer to your e-mail dated 4 September 2019 in which you make a request for access to documents, registered on 4 September 2019 under the above-mentioned reference number.

We also refer to our clarification letter sent to you on 17 September 2019.

We further refer to your email sent on 1 October 2019 by which we became aware of your reply to our clarification request published in Ask the EU.

Finally, we refer to our letter extending the deadline for replying sent to you on 22 October 2019 in accordance with Article 7(3) of Regulation (EC) No 1049/2001.

1. Scope of your request

Initially, in your application you requested the following:

- [1]. 'All details, correspondence and minutes relating to meetings between DG SANTE and Everis since 1 May 2013.
- [2]. All contracts made between DG SANTE and Everis since 1 May 2013.
- [3]. All details, correspondence and minutes relating to meetings between DG SANTE and representatives of ATOS, De La Rue, IBM, Honeywell, Allexis, and other companies involved in the secure printing industry or IT solutions for traceability since 1 May 2013.'

You have further elaborated point 3 of your request through the site Ask the EU, as we became aware through your email sent to us on 1 October 2019:

‘All details, correspondence and minutes relating to meetings between DG SANTE and representatives of ATOS, De La Rue, SICPA, Worldline, Inexto, Dentsu Aegis, NTT Data, Honeywell, IBM, and Sovereign Border Solutions since 1 May 2013.

In addition, all details, correspondence, and minutes related to meetings between DG SANTE and companies who contracted or submitted a tender to build parts of the EU's Track and Trace system for tobacco products.’

2. Identification and assessment of the relevant documents

We have identified 70 documents falling within the scope of your request. You will find attached a table listing the identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001 regarding public access to documents¹ (‘the Regulation’).

Having examined these documents under the provisions of the Regulation and consulted the originators of the documents received from third parties, we have come to the conclusion that:

- Full access can be granted to documents No 1 to 35;
- Partial access can be granted to document No 36 and to documents No 39 to 70 as their full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.
- No access can be granted to documents 37 and 38 as it is prevented by one of the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

We enclose the hyperlinks to the documents No 1 to 35 and the redacted version of documents that can be only partially disclosed.

You may reuse the documents requested free of charge for non-commercial and commercial purposes provided that the source is acknowledged and that you do not distort the original meaning or message of the documents. Please note that the Commission does not assume liability stemming from the reuse.

Please note that some documents were received by the Commission from third parties. They are disclosed for information only and cannot be re-used without the agreement of the originator, who holds a copyright on it. They do not reflect the position of the Commission and cannot be quoted as such.

3. Reason for refusal

Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

Document No 37 consists of an exchange of e-mails between the Commission, Everis and Delarue, while document No 38 originates from Inexto. The originators of the documents have been consulted, in accordance with Article 4(4) of the Regulation, to assess whether an exception under Article 4 of the Regulation is applicable.

¹ Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43). Ref. Ares(2019)4868543 - 25/07/2019.

Commission services did not receive a reply from the originators of the documents; Therefore the documents were assessed taking into account legitimate interests of the originators on the basis of the information in our possession.

According to Article 4(2) of the Regulation (EC), access to a document may be refused where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure.

Documents No 37 and 38 contain information of a commercially sensitive nature, the disclosure of which would pose a serious risk of harming the commercial interests of the third parties from which they originated. They therefore fall under the scope of the exception protecting the commercial interests of a legal person and cannot be disclosed.

We have considered whether partial access could be granted to documents No 37 and 38, but we consider that they are fully covered by the above-mentioned exception.

4. Reasons for partial refusal

Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

Document No 40 is a contract signed between DG SANTE and Everis Spain.

It includes details that could, if disclosed to the public, harm the commercial interests of the contractual parties, and therefore it can only be disclosed, redacted of the parts falling under the scope of the exception laid down in Article 4(2), first indent of the Regulation, namely the detailed breakdown of the contractual fees.

Documents No 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69 were received by the Commission from EMA, which was consulted in accordance with Article 4(4) of the Regulation, to assess whether an exception under Article 4 of the Regulation is applicable.

The requested documents relate to the execution and progress of an IT project which forms the subject of a framework contract deriving from an EMA public procurement procedure (framework contract number EMA/2016/IM). The Agency considers that certain information presented in these documents contains sensitive commercial information related to the consortium members participating in the related contract and is not publicly available.

In particular, these documents contain reference to methodologies, working modalities, cost components, the strengths and weaknesses of deliverables and the success of the implementation of the project to date.

In accordance with the first indent of Article 4(2) of the Regulation access to certain documents shall be refused if its disclosure would undermine the commercial interests of a natural or legal person, including intellectual property.

According to the assessment of Commission services, taking into account the opinion of EMA, the above-mentioned information falls under the above-mentioned exception.

Documents 42, 44, 48, 50, 52, 54, 56, 60, 62, 64, 66, 68, 70 contain information which is considered as commercially sensitive and which therefore also falls under the exception to the right of access to documents laid down in Article 4(2), first indent of the Regulation.

The documents listed above are therefore disclosed redacted of such information.

Protection of the privacy and integrity of the individual - Article 4(1)(b) of Regulation (EC) No 1049/2001

Pursuant to Article 4(1)(b) of the Regulation, 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 European Union legislation regarding the protection of personal data.

The applicable legislation in this field is Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC² ('Regulation 2018/1725').

Some of the documents to which you request access contain personal data, in particular names, e-mail addresses, phone numbers and functions.

Indeed, Article 3(1) of Regulation 2018/1725 provides that personal data 'means any information relating to an identified or identifiable natural person [...]'. The Court of Justice has specified that any information, which by reason of its content, purpose or effect, is linked to a particular person is to be considered as personal data³.

Please note in this respect that the names, signatures, functions, telephone numbers and/or initials pertaining to staff members of an institution are to be considered personal data⁴.

In its judgment in Case C-28/08 P (Bavarian Lager)⁵, the Court of Justice ruled that when a request is made for access to documents containing personal data, the Data Protection Regulation becomes fully applicable⁶.

Pursuant to Article 9(1)(b) of Regulation 2018/1725, 'personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if '[t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject's legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests'.

Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation 2018/1725, can the transmission of personal data occur.

According to Article 9(1)(b) of Regulation 2018/1725, the European Commission has to examine the further conditions for a lawful processing of personal data only if the first condition is fulfilled, namely if the recipient has established that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European

² Official Journal L 205 of 21.11.2018, p. 39.

³ Judgment of the Court of Justice of the European Union of 20 December 2017 in Case C-434/16, *Peter Nowak v Data Protection Commissioner*, request for a preliminary ruling, paragraphs 33 to 35, [ECLI:EU:C:2017:994](#).

⁴ Judgment of the General Court of 19 September 2018 in case T-39/17, *Port de Brest v Commission*, paragraphs 43 to 44, [ECLI:EU:T:2018:560](#).

⁵ Judgment of 29 June 2010 in Case C-28/08 P, *European Commission v The Bavarian Lager Co. Ltd*, EU:C:2010:378, paragraph 59.

⁶ Whereas this judgment specifically related to 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, the principles set out therein are also applicable under the new data protection regime established by Regulation 2018/1725.

Commission has to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your request, you do not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced.

Notwithstanding the above, please note that there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by disclosure of the personal data concerned.

As to the signatures of staff members of the Commission and which are biometric data, there is a risk that their disclosure would prejudice the legitimate interests of the persons concerned.

Therefore, documents No 36, 39, 40, 42, 44, 46, 48, 50, 52, 54, 56, 57, 58, 60, 62, 64, 66, 68, 70 are disclosed redacted of the elements which contain personal data.

5. Overriding public interest

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

Secretariat-General

Unit C.1. 'Transparency, Document Management and Access to Documents'

BERL 7/076

B-1049 Bruxelles, or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,



Anne BUCHER

Enclosure: List of documents;
Documents that can be partially disclosed listed under Section 2 (only enclosed to the electronic version of this letter).