EUROPEAN COMMISSION

Brussels, 24.7.2019
C(2019) 5653 final

[redacted]
00156 Roma
Italy

DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) NO 1049/2001[1]

Subject: **Your confirmatory application for access to documents under Regulation (EC) No 1049/2001 - GESTDEM 2019/1822**

Dear [redacted]

I refer to your email of 29 April 2019, registered on 3 May 2019, in which you submit a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents[2] (hereafter 'Regulation (EC) No 1049/2001').

1. SCOPE OF YOUR REQUEST

In your initial application of 25 March 2019, addressed to the Directorate-General for Environment, you requested access to all the documents related to the infringement procedures launched by the European Commission against Italy in respect of Directive 2010/63/EU[3] .

In particular, you expressed your interest for the reasons, status to date, communications, possible fines and the part of the procedures in question which were triggered by non-governmental organisations such as the European Animal Research Association and Research4Life.

[1] Official Journal L 345 of 29.12.2001, p. 94.
[2] Official Journal L 145 of 31.5.2001, p. 43.
[3] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, Official Journal L 276 of 20.10.2010, p. 33–79

The European Commission has identified the following two files as falling under the scope of your request:

- infringement procedure 2016/2013; and
- infringement procedure 2013/0042.

In its initial reply of 9 April 2019 concerning the part of your request related to infringement procedure 2016/2013, the Directorate-General for Environment refused access to the documents pertaining to that investigation, pursuant to Article 4(2), third indent of Regulation (EC) No 1049/2001, on the ground that it was pending at the stage of the Reasoned Opinion.

In its complementary initial reply of 25 April 2019 in relation to the part of your request concerning the currently archived infringement procedure 2013/0042, the Directorate-General for Environment:

- granted full access to the Letter of Formal Notice, the related replies of the Italian authorities of 21 August 2013, 10 December 2013 and 6 March 2014, and the extract from the Italian Official Journal no 61 of 14 March 2014[4]; and
- refused partial access to the Reasoned Opinion and full access to the replies of the Italian authorities of 12 February 2013[5] and 26 May 2014[6], on the basis of the exception of Article 4(2), third indent of Regulation (EC) 1049/2001 concerning the protection of the purpose of investigations, after consultation of the Italian authorities in accordance with Article 4(4) and (5) of the said regulation.

In your confirmatory application, you request a review of this position. You underpin your request with detailed arguments, which I will address in the corresponding sections below.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION (EC) NO 1049/2001

When assessing a confirmatory application for access to documents submitted pursuant to Regulation (EC) No 1049/2001, the Secretariat-General conducts a fresh review of the reply given by the Directorate-General concerned at the initial stage.

Following this review, I regret to inform you that I have to confirm the initial decision of Directorate-General for Environment to refuse access to the *requested documents pertaining to infringement procedure 2016/2013* based on the exception concerning the protection of the purpose of investigations, provided under Article 4(2), third indent of Regulation (EC) No 1049/2001, for the reasons set out below.

[4] Containing the publication of the Legislative Decree of 4 March 2014, together with a correlation table.
[5] To the Letter of Formal Notice.
[6] To the Reasoned Opinion.

However, I am pleased to release the *reply of the Italian authorities of 26 May 2014*, the *the Reasoned Opinion* (including its withheld third paragraph) as well as *the Reply of the Italian authorities of 12 February* 2013, subject to the sole redaction of personal data, in accordance with the exception laid down in Article 4(1)b for the protection of privacy and the integrity of the individual as detailed below.

2.1. Protection of the purpose of investigations

Article 4(2), third indent of Regulation (EC) No 1049/2001 provides that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of […] the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure.'

The Court of Justice held that '[…] infringement procedures are […] a type of procedure which, as such, has characteristics precluding full transparency being granted in that field and which therefore has a special position within the system of access to documents'[7].

Consequently, pursuant to settled case law, '[…] it can be presumed that the disclosure of the documents concerning an infringement procedure during its pre-litigation stage risks altering the nature of that procedure and changing the way it proceeds and, accordingly, that disclosure would in principle undermine the protection of the purpose of investigations, within the meaning of the third indent of Article 4(2) of Regulation [EC] No 1049/2001.[8],

The General Court further stressed that '[…] the Member States are entitled to expect the European Commission to guarantee confidentiality during investigations which might lead to an infringement procedure. This requirement of confidentiality remains even after the matter has been brought before the Court of Justice, on the ground that it cannot be ruled out that the discussions between the Commission and the Member State in question regarding the latter's voluntary compliance with the Treaty requirements may continue during the court proceedings and up to the delivery of the judgment of the Court of Justice. The preservation of that objective, namely an amicable resolution of the dispute between the Commission and the Member State concerned before the Court of Justice has delivered judgment, justifies refusal of access […] on the ground of protection of the public interest relating to inspections, investigations and court proceedings […]'.[9]

Nevertheless, when the above-mentioned general presumption does not or no longer applies, it is the duty of the European Commission to examine individually and specifically whether the requested documents can be fully disclosed publicly[10].

[7] See judgment of 14 November 2013, *LPN and Finland* v *European Commission*, C - 514/11 P and C - 605 / 11 P, EU:C:2013:738, paragraph 55.
[8] *Ibid*, paragraph 65.
[9] Judgment of 11 December 2001, *Petrie and Others* v *European Commission*, T-191/99, EU:T:2001:284, paragraph 68.
[10] See *inter* alia, judgment of 16 July 2015, *ClientEarth* **v** *European Commission*, C-612/13 P, EU:C:2015:486, paragraph 82.

In this instance, the documents to which you request access relate to two infringement procedures, namely infringement procedure 2016/2013 which is still pending and closed infringement procedure 2013/0042.

In its initial reply, the Directorate-General for environment refused access to the documents related to infringement procedure 2016/2013 on the basis of a general presumption against disclosure resulting from Article 4(2), third indent of Regulation (EC) No 1049/2001. I must confirm this position on the ground that infringement procedure 2016/2013 is still pending, in light of the above-mentioned case law.

As far as the documents related to infringement procedure 2013/0042 are concerned, as they are no longer protected by such a general presumption of confidentiality, the Directorate-General for environment granted full access to them, subject to a withheld part of the Reasoned Opinion and two replies of the Italian authorities of 12 February 2013 and 26 May 2014.

The withheld part of the Reasoned Opinion and the two replies of the Italian authorities in question were refused, after consultation of the Italian authorities in accordance with Article 4(4) and (5) of Regulation (EC) No 1049/2001, on the ground that those documents contain substantive information inextricably linked to the still pending procedure 2016/2013.

In the framework of this consultation, I would like to reassure you, that, contrary to your assumption[11], your identity was not released. Pursuant to the European Commission's established practice and in accordance with Regulation (EU) 2018/1725[12], the identity of applicants is not disclosed in the course of consultations of third parties under Article 4(4) and (5) of Regulation (EC) No 1049/2001. In this context, the third party originator of the requested document(s) is, indeed, merely informed of the submission of the application for access and requested to provide its position as to the requested public disclosure within a specific time-limit.

At the confirmatory stage, the Italian authorities were consulted again and amended their initial position as detailed below.

a) Position of the Italian authorities

Following their re-consultation pursuant to Article 4(4) and (5) of Regulation (EC) No 1049/2001, the Italian authorities have waived their initial opposition to the disclosure of their reply of 26 May 2014.

[11] See the last paragraph of your confirmatory application.

[12] Regulation 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/ECOfficial Journal L 295 of 21 November 2018, p.39, hereinafter 'Regulation (EU) 2018/1725'.

The Italian authorities maintained nevertheless their opposition to the disclosure of their reply of 12 February 2013, based on Article 4(2), third indent of Regulation (EC) No 1049/2001, on the ground that it would seriously undermine pending procedure 2016/2013.

b) Prima Facie Assessment of the European Commission

The European Commission carried out a *prima facie* assessment of the reasoning put forward by the Italian authorities in light of the provisions of Regulation (EC) No 1049/2001.

In this context, the European Commission first notes that the reply of the Italian authorities of 12 February 2013, pertains to closed investigation 2013/0042 regarding the lack of transposition by Italy of Directive 2010/63.

Moreover, this document does not seem to contain any substantive elements as regards the incorrect transposition by Italy of the said directive, as currently assessed under pending infringement procedure 2016/2013.

Furthermore, whereas both closed infringement procedure 2013/0042 and ongoing infringement procedure 2016/2013 concern the issue of the transposition by Italy of the same act, namely Directive 2010/63/EU, they had two distinct purposes. Whilst the latter focus on the improper transposition of the directive in question by Italy, the former concerned exclusively the issue of its lack of transposition into the Italian legislation. Both procedures cannot therefore be considered, at first sight, as inextricably linked.

Therefore, the disclosure of the arguments raised by Italy regarding the reasons underlying the lack of transposition in the framework of a procedure closed more than five years ago do not seem likely to undermine the distinct purpose of the currently pending investigation under infringement procedure 2016/2013, which consists in assessing whether the transposition of Directive 2010/63/EU into the Italian legislation is proper.

This *prima facie* conclusion seems further reinforced by the fact that, in substance, the reply of the Italian authorities of 12 February 2013 is rather brief and drafted in quite general terms, referring to a political situation which was likely of public knowledge at the time.

Against this background, the arguments raised by Italy in the framework of the closed procedure for lack of transposition do not appear, *at first sight*, to remain applicable in the context of the ongoing procedure for improper transposition of Directive 2010/63/EU.

According to the European Commission's assessment, the exception of Article 4(2), third indent of Regulation (EC) No 1049/2001, concerning the protection of the purpose of investigations does not therefore, at first sight, seems to apply to the document in question.

In light above the above, access to the third paragraph of the Reasoned Opinion sent by the European Commission to the Italian authorities, cannot therefore be refused on the mere ground that its reflects the position expressed in the reply of 12 February 2013 from the Permanent Representation.

Consequently, access is, hereby, granted to the three requested documents pertaining to infringement procedure 2013/0042, subject to the sole redaction of personal data, in accordance with Article 4(1)(b) of Regulation (EC) No 1049/2001, as detailed below.

2.2. Protection of privacy and the integrity of the individual

Article 4(1)(b) of Regulation 1049/2001 provides that '[t]he institutions shall refuse access to a document where 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 (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/EC.[13]

In the *Psara* case, the General Court reiterated that Article 4(1)(b) 'is an indivisible provision [which] requires that any undermining of privacy and the integrity of the individual must always be examined and assessed in conformity with the legislation of the Union concerning the protection of personal data, in particular with Regulation 45/2001' and that '[it] establishes a specific and reinforced system of protection of a person whose personal data could, in certain cases, be communicated to the public […].[14]'

Notwithstanding the fact that this judgment referred to Regulation (EC) No 45/2001, it applies by analogy to Regulation (EU) 2018/1725, as, in principle, the rest of the case law pertaining to the former.

Article 3(1) of Regulation (EU) 2018/1725 provides that personal data 'means any information relating to an identified or identifiable natural person […]'. The Court of Justice ruled that any information, which due to its content, purpose or effect, is linked to a particular person, qualifies as personal data[15].

[13] Official Journal L 205 of 21.11.2018, p. 39, hereafter 'Regulation (EU) 2018/1725'.
[14] Judgment of 25 September 2018, *Maria Psara and Others* v *European Parliament*, T-639/15 to T-666/15 and T-94/16, EU:T:2018:602, paragraph 65.
[15] Judgment of 20 December 2017, C-434/16, *Peter Novak* v *Data Protection Commissioner*, EU:T:2018:560, paragraphs 33-35

In the *Rechnungshof* case law, the Court of Justice further confirmed that 'there is no reason of principle to justify excluding activities of a professional […] nature from the notion of private life'[16].

The General Court also stressed that '[t]he Court previously held that derogations from the protection of personal data must be interpreted strictly'[17].

In this instance, the letters of replies originating from the Italian authorities and the Reasoned Opinion contain the names, surnames and handwritten signatures of individuals.

Public disclosure of these personal and biometric data would consequently constitute processing (transfer) of personal data within the meaning of Article 9(1) (b) of Regulation (EU) 2018/1725.

Pursuant to this provision, 'personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if […] the 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 both fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation (EU) 2018/1725, can the transmission of personal data occur.

According to settled case-law, the condition of necessity laid down in Article 9(1)(b) of Regulation (EU) 2018/1725 requires the demonstration by the applicant that the transfer of personal data is the most appropriate of the possible measures for attaining his/her objective, and that it is proportionate to that objective.'[18]

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 subjects' 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.

[16] Judgment of 20 May 2003, C-465/00, C-138/01 and C-139/01, *Rechnungshof* v *Österreichischer Rundfunk and others*, EU:C:2003:294, paragraph 73.
[17] Judgment of 25 September 2018, *Maria Psara and Others* v *European Parliament*, T-639/15 to T-666/15 and T-94/16, *op. cit.*, paragraph 68.
[18] Judgment of 15 July 2015, *Dennekamp* v *Parliament*, T-115/13, EU:T:2015:497, paragraph 77.

Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data included in the Replies of the Italian authorities and the Reasoned Opinion, 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 such a disclosure.

3. OVERRIDING PUBLIC INTEREST IN DISCLOSURE

Whereas Article 4(1)b is an absolute exception which cannot be set aside, the exception laid down in Article 4(2), third indent of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

In your confirmatory application, you allege the existence of an overriding public interest on the grounds that (1) your organisation represents many Italian citizens asking for the abolition of animal experiments; (2) an opinion of the Italian Commission XII 'Igiene e Sanità' of 12 March 2019 requesting amendments in the Italian legislation; (3) the lack of transparency on the reasons underlying the infringement procedure against Italy; (4) an online petition signed by 17000 citizens in favour of the repeal of the opinion and respect of the transposition of Directive 63/2010/EU; and (5) the required public awareness of the actual situation, including animal welfare organisations and not only 'interested lobbies with financial interests'.

Pursuant to settled case law, whereas the overriding public interest capable of justifying the disclosure of requested documents must not necessarily be distinct from the principles which underlie Regulation[(EC)] No 1049/2001, such general considerations cannot, nevertheless, provide an appropriate basis for establishing that, in the present case, the principle of transparency is so pressing as to prevail over the reasons justifying the refusal to disclose the documents in question[19].

Having regard to the foregoing considerations, it appears that none of the arguments that you put forward establish the existence of an overriding public interest within the meaning of Regulation (EC) No 1049/2001.

Nor have I been able to identify any public interest capable of overriding the interest protected by Article 4(2), third indent of Regulation (EC) No 1049/2001. This is notwithstanding the fact that the European Commission welcomes the public's interest regarding the transposition of Directive 63/2010/EU and has been promoting animal welfare within the limits of its responsibilities.

[19] Judgment of 14 November 2013, *LPN and Finland* v *European Commission*, C-514/11P and C-605/11P, EU:C:2013:738, paragraphs 92 to 94.

The fact that the requested documents relate to an administrative procedure and not to any legislative act, for which the Court of Justice has acknowledged the existence of wider openness[20], provides further support to this conclusion.

Moreover, the fact that the European Commission has kept, to some extent, the public informed of the substance and the various stages of the infringement procedure in question via its dedicated portal for infringements only reinforces this conclusion.

4. PARTIAL ACCESS

In accordance with Article 4(6) of Regulation[(EC)] No 1049/2001, (further) partial access is hereby granted to the Reasoned Opinion and the Reply of the Italian authorities of 12 February 2013.

However, for the reasons explained above, no (further) meaningful partial access is possible without undermining the interests described above.

As far as the refused documents pertaining to infringement procedure 2016/2013 are concerned, they do not fall within an obligation of disclosure, in full, or in part, pursuant to settled case law, as they are covered by a general presumption of non-disclosure[21]. Consequently, I have come to the conclusion that these documents are covered in their entirety by the invoked exception to the right of public access.

5. DISCLOSURE AGAINST THE EXPLICIT OPINION OF THE ITALIAN AUTHORITIES

As the decision to partially disclose the Reply of 12 February 2013 and the third paragraph of the Reasoned Opinion (insofar as it reflects the substance of the latter) is taken against the objections of the Italian authorities expressed in the framework of their consultation at the initial and confirmatory level in accordance with Article 4(4) and (5) of Regulation (EC) No 1049/2001 as explained above, the European Commission will inform them of its decision.

The institution will not grant such partial disclosure until a period of ten working days has elapsed from the formal notification of this decision to the Italian authorities, in accordance with Article 5(6) of the implementing provisions of Regulation (EC) No 1049/2001.

This time-period will allow the Italian authorities to inform the European Commission whether they will object to the partial disclosure using the remedies available to it, *i.e*. an application for annulment and an application for interim measures before the General Court.

[20] Judgment of 29 June 2010, *European Commission* v *Technische Glaswerke Ilmenau Gmbh*, C-139/07 P, EU:C:2010:376, paragraph 60.
[21] Judgment of 28 June 2012, *European Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 133.

Once this period has elapsed, and should the Italian authorities have not signalled their intention to avail themselves of the remedies at their disposal, the European Commission will forward the two remaining redacted documents to you.

6. MEANS OF REDRESS

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

CERTIFIED COPY
For the Secretary-General,

[redacted]

EUROPEAN COMMISSION

For the Commission

[redacted]

Enclosures: (3)