EUROPEAN COMMISSION

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DECISION OF THE SECRETARY-GENERAL ON BEHALF OF THE COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) N° 1049/2001[1]

Subject: **Your confirmatory application for access to documents – GESTDEM 2017/4988**

Dear Mr Beckett,

I refer to your e-mail of 10 September 2017, registered on 20 September 2017, wherein 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 1049/2001').

1. SCOPE OF YOUR REQUEST

In your initial application of 31 August 2017, you requested access to *documents which contain [a]ll information submitted via the EU-CEG by British American Tobacco for and in support of its notification of the iFuse range of products under Article 19 of Directive 2014/40/EU, including all attachments submitted.*

[1] Official Journal L 345 of 29.12.2001, p. 94.
[2] Official Journal L 145 of 31.5.2001, p. 43.

In its reply of 8 September 2017, the Directorate-General for Health and Food Safety ('DG SANTE') informed you that the information submitted by manufacturers and importers through the EU-CEG platform[3] under Article 19 of Directive 2014/40/EU is provided to the Member States and not to the Commission, and that the latter is only given access to this information by Member States for the purposes of applying the Directive.

DG SANTE also explained that, in any case, the disclosure of information related to novel tobacco products[4] would likely cause significant economic harm to the companies that have submitted it. In light of this, DG SANTE considered that the use of the exception under Article 4(2), first indent, of Regulation 1049/2001 on the grounds of protecting commercial interests was justified in respect to any information in the database, which had been submitted under Article 19 of Directive 2014/40/EU through the EU-CEG platform.

For the sake of completeness, I note that the initial reply of DG SANTE covered both your initial application registered under reference GESTDEM 2017/4745 (iQOS notifications under Directive 2014/40/EU) and your initial application registered under reference GESTDEM 2017/4988 (Notification of iFuse products under Directive 2014/40/EU). Nevertheless, in your confirmatory application of 10 September 2017, you only request the review of the part of DG SANTE's initial reply concerning the notification of iFuse products. Consequently, the part of DG SANTE's initial reply concerning the iQOS notifications falls outside the scope of your confirmatory application and, therefore, outside the scope of this confirmatory decision.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION 1049/2001

When assessing a confirmatory application for access to documents submitted pursuant to Regulation 1049/2001, the Secretariat-General conducts a fresh review of the reply given by the Directorate-General concerned at the initial stage.

As a preliminary comment, I would like to clarify that, pursuant to Article 5(1) of Directive 2014/40/EU[5], the Member States require manufacturers and importers of tobacco products to submit to the Member States' *competent authorities* certain information concerning such products.

[3] The EU Common Entry Gate ('EU-CEG') platform is designed to reduce administrative burden for companies and regulators, and make it easier to compare data. The tool was developed by the European Commission, working closely with Member States and industry stakeholders. It became operational in May 2016.

[4] The novel tobacco products are tobacco products which are not listed under Article 2(14)(a), of Directive 2014/40/EU and which are placed on the market after 19 May 2014.

[5] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1–38).

The final addressees of the information submitted under Directive 2014/40EU are therefore the relevant authorities in the Member States and not the Commission. Indeed, the Directive does not provide for the necessary involvement of the Commission in the respective collection process.

The manufacturers and importers of tobacco products submit the required information via the EU-CEG platform. I note that the creation of the EU-CEG platform (by the Commission) is not explicitly envisaged in Directive 2014/40/EU. It was established at the Commission's own initiative, in order to ensure that manufacturers and importers submit the required data to the Member States by using the same electronic format, thereby facilitating the collection process and mitigating the potential incoherence in the data provided by different submitters.

Following your confirmatory application, the Commission carried out a more specific search in the database of the EU-CEG platform based on the information provided in your confirmatory application and using the available (routine) search functions. That search, performed for each of the 28 Member States, did not result in the identification of any data related to tobacco products notified under Article 19 of Directive 2014/40/EU that contain the term 'iFuse' in their brand or sub-brand name description.

Please note in this respect that the search operations available in the database of the EU-CEG platform are limited to essential filtering options providing Member States with a general overview supporting them in performing the required product assessments. The identification of a specific tobacco product (and filtering out and extracting its respective data) is possible at the level of brand and/or sub-brand name of the product and/or its type, but not, for example, at the level of the types of information the manufacturers and importers have to provide under Article 19 of Directive 2014/40/EU, or at the level of possible links between various tobacco products.

In this context, I note that the question regarding the possible status of information stored in databases as a *document* within the meaning of Regulation 1049/2001 has already been subject to an assessment by the General Court. In its ruling in the *Typke* case, the latter established that *in the event of an application for access designed to have the Commission carry out a search of one or more of its databases using search criteria specified by the applicant, the Commission is obliged, subject to the possible application of Article 4 of Regulation No 1049/2001, to accede to that request, if the requisite search can be carried out using the search tools which it has available for the database in question*[6].

[6] Judgment of the General Court of 2 July 2015 in case T-214/13, *Typke v Commission*, (ECLI:EU:T:2015:448), paragraph 56.

With this judgment, the General Court confirmed the previous judgment in the *Dufour* case, where the Court stated that *anything that can be extracted from a database by means of a normal or routine search may be the subject of an application for access*[7].

Furthermore, I would like to bring to your attention the recent *Typke* judgment, where the Court of Justice took the position that the *routine* character of an operation which determines whether information extracted from a database is a document, is determined by whether the operation has been made available to final users for general use[8]. As indicated above, in the database of the EU-CEG platform only very limited search operations are available to the final users of the platform.

Consequently, as the data to which you request access could not be extracted from the database of the EU-CEG platform by means of a normal or routine search operation, using the search tools available, I confirm that the Commission has not identified any documents held by it that would fall under the scope of your request.

I therefore confirm that, as specified in Article 2(3) of Regulation 1049/2001, the right of access as defined in that Regulation applies only to existing documents in the possession of the institution. Given that no documents falling under the scope of your request have been identified at the confirmatory stage, the Commission is not in a position to handle your confirmatory application.

In your confirmatory application, you argue that *if the Commission holds information as requested in [your] 1049 request, and the submitter has not marked that information 'confidential' then there is no reason for that information to be withheld from the public based on potential commercial consequences for the submitter. If the submitter has marked this information confidential, but it cannot be said to be so within the boundaries set by 2015/2186, then the Commission should also release this information to the public.*

As indicated above, these comments are irrelevant, as the Commission does not hold any documents falling under the scope of your application.

Please allow me to point out however, for the sake of completeness, that, in general, submissions under Directive 2014/40/EU contain commercially sensitive business information which is accompanied by a confidentiality clause when it is provided to the Member States through EU-CEG platform. Indeed, whilst the above-mentioned Directive stipulates that Member States ensure the publication of a non-confidential version of the data provided by manufacturers and importers, such publication cannot take place earlier than after a detailed examination of the data by the Member States' authorities that were the addressees of the data.

[7] Judgment of the General Court of 26 October 2011 in case T-436/09, *Dufour v European Central Bank*, (ECLI:EU:T:2011:634), paragraph 153.

[8] Judgment of the Court of 11 January 2017 in case C-491/15P, *Typke v Commission*, (ECLI:EU:C:2017:5), paragraph 36.

3. 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 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION

For the Commission
Alexander ITALIANER
Secretary-General