



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels  
sante.ddg1.b.2/JH/kd(2017)4885598

*By registered letter with acknowledgement  
of receipt*

Dear Mr Beckett,

**Subject: Your applications for access to documents –  
Ref GestDem No 2017/4745 and Ref GestDem No 2017/4988**

I refer to your two request for access to documents; the first of which is dated 17/08/2017, registered on 18/08/2017 under the reference number Ares(2017)4084330, concerning application GestDem 2017/4745, and the second of which is dated 31/08/2017, registered on 01/09/2017 under the reference number Ares(2017)4275138, concerning application GestDem 2017/4988.

Your first request concerns: *All submissions made by Phillip Morris International or its subsidiaries to Public Health England related to the iQOS family of products, including the iQOS device, the HEETS and Marlboro Heatsticks brands of heated tobacco sticks, and any other related product, under Article 19 of Directive 2014/40/EU, to the EU CEG portal, including any attachments.*

Your second request concerns: *All 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.*

The documents which you seek to obtain under your requests relate to information on novel tobacco products that has been recorded by manufacturers and importers, as required under Article 19 of Directive 2014/40/EU, and that was sent via the EU-CEG to the Member States in which such novel products are intended to be placed on the market.

At the outset, I would like to note that the information submitted under Article 19 of Directive 2014/40/EU is provided to Member States and not to the European Commission. The latter is only given access to this information by Member States for the purposes of applying the Directive.

**Mr Peter Beckett**  
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With respect to your applications for access to documents, I refer you to Article 4(2), first indent, of Regulation (EC) No 1049/2001, which stipulates that:

*"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, unless there is an overriding public interest in disclosure."*

The product information submitted by manufacturers and importers under Article 19 of Directive 2014/40/EU relates to novel tobacco products, that is, products which are not listed under Article 2(14), first indent, and which are placed on the market after 19 May 2014.

The disclosure of information related to such products would allow the instructed public to gather important information of business relevance, such as an indication of detailed product compositions, production methods and technological characteristics. Therefore, disclosing this information would likely cause significant economic harm to the companies that have submitted it. Moreover, the notification period laid down in Article 19 of Directive 2014/40/EU requires that, subsequent to the submission of information by manufacturers and importers, the novel product concerned cannot be made available to consumers within six months of the submission date. This means that, in any case, disclosure of information related to novel products would also have the potential of giving a competitive advantage to other companies that are active in the sector.

In light of the aspects outlined above, I consider that the use of the exception under Article 4(2), first indent, of Regulation (EC) No 1049/2001 on the grounds of protecting commercial interests is justified with respect to the documents to which you request access. Therefore, both of your access requests under Regulation (EC) No 1049/2001 to the documents mentioned above must be denied.

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](mailto:sg-acc-doc@ec.europa.eu)

Yours sincerely,



Xavier Prats Monné