

SERVICE LEVEL AGREEMENT

between

the European Commission (hereinafter "the Commission"), represented by the Director-General for Health and Food safety, Xavier Prats Monné,

on the one part,

and

the Republic of Bulgaria (hereinafter "the Member State"), represented by the Director of Tobacco and Tobacco Products Institute, Mrs. Mariya Kasheva,

on the other part,

on the storage of data on tobacco products, on novel tobacco products and on herbal products for smoking

PREAMBLE

Whereas:

- (1) Directive 2014/40/EU of the European Parliament and of the Council¹ requires manufacturers and importers of tobacco products and electronic cigarettes and refill containers to submit certain information on those products to the Member States.
- (2) In order to ensure the uniform application of Articles 20(13) and 5(5) of Directive 2014/40/EU, common electronic formats have been established by Commission Implementing Decision (EU) 2015/2183² for electronic cigarettes and refill containers and by Commission Implementing Decision (EU) 2015/2186³ for

¹ 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).

² Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (OJ L 309, 26.11.2015, p. 15).

³ Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products (OJ L 312, 27.11.2015, p.5).

tobacco products. In particular, those decisions provide for the establishment and operation of a common electronic entry gate ("the EU-CEG"). Member States are to ensure that all data submitted by manufacturers and importers under Directive 2014/40/EU is submitted through the EU-CEG, including resubmissions and corrections.

- (3) In addition, according to the fifth recital of Implementing Decision (EU) 2015/2186, it should be possible for Member States to use the tools established in that Decision for the purposes of submitting information on novel tobacco products and herbal products for smoking in accordance with Article 19 and 22 of Directive 2014/40/EU. Consequently, the EU-CEG was established in a manner that allows it to be used for the submission of data relating to those products also.
- (4) While Member States are fully responsible for gathering, verifying, analysing, storing and disseminating data, Implementing Decisions (EU) 2015/2183 and (EU) 2015/2186 provide for the possibility of storing the data submitted to Member States through the EU-CEG at Commission facilities, provided those Member States have signed a service level agreement with the Commission. Such a possibility for storage should, in particular, apply to data on electronic cigarettes and refill containers as well as data on tobacco products, including novel tobacco products and herbal products for smoking.
- (5) The essential conditions governing the Commission's storage of data do not vary depending on whether the data relates to electronic cigarettes and refill containers or to tobacco products, including novel tobacco products and herbal products for smoking. Therefore, a single model agreement has been prepared that covers information submitted in respect of each of those products.
- (6) The provision of such services is regulated by this Agreement, to be signed by the duly authorised representatives of the Commission and the Member State choosing to make use of the Commission storage facilities.
- (7) The Agreement does not affect the legal obligations of the Member State and the Commission, as set out in Directive 2014/40/EU and other relevant Union legislation, including the protection of data, especially trade secrets, confidential and personal data. The Agreement should always be interpreted in such a way as to ensure compliance with applicable Union and national legislation.

The contracting Parties have agreed as follows:

Article 1

Subject matter

1. This Agreement applies to data relating to the following products category:
 - (a) Tobacco products, including novel tobacco products and herbal products for smoking;

2. This Agreement lays down the terms and conditions concerning the data storage facilities offered by the Commission to Member States for data submitted by the submitting parties under Directive 2014/40/EU through the EU-CEG with respect to the category of products referred to in paragraph 1.
3. This Agreement clarifies the roles and responsibilities of the Commission and the Member State in relation to the functioning and use of the storage facilities covered by this Agreement and the protection of data.

Article 2

Definitions

1. All terms in this Agreement derived from or defined in Directive 2014/40/EU and in Implementing Decisions (EU) 2015/2183 and (EU) 2015/2186 shall have the same meaning as under those acts.
2. For the purpose of this Agreement:
 - (a) "submitting parties" means the manufacturers and importers of one or more of the following products, namely, of tobacco products, of novel tobacco products, of electronic cigarettes and refill containers and of herbal products for smoking that submit information to the Member State through the EU-CEG;
 - (b) "national repository" means an autonomous section of the storage database hosted by the Commission which is assigned to the Member State and used to store data submitted to it through the EU-CEG;
 - (c) "national administrator" means the physical person(s) appointed by the Member State as responsible for all access to the national repository, excluding Commission access provided for in this Agreement;
 - (d) "access right" means the possibility to view information stored in the national repository and to extract reports created on the basis of the data stored;
 - (e) "personal data" means any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;
 - (f) "service maintenance" means Commission maintenance of the complete EU-CEG, including the national repository, and database index rebuilding, hardware and software upgrades.

Article 3

Responsibilities and tasks of the Commission

The Commission is responsible for:

- (a) providing the Member State with a possibility to store the data submitted to it through the EU-CEG in a national repository within the Commission data storage facility. The national repository shall be technically separated from that of other Member States and shall, where applicable, consist of separate sections for the two product categories covered by this Agreement and listed in Article 1(1);
- (b) setting up an authentication system and granting access right(s) to the national administrators appointed by the Member State under Article 4(c);
- (c) providing as a minimum 95% accessibility to the national repository on a 24/7 basis, including service maintenance;
- (d) adopting all measures necessary to protect the safety and integrity of the environment of the national repository, such as adequate firewalls, encrypted codes, antivirus software and users authentication;
- (e) ensuring the reestablishment of the service as soon as possible, normally within 2 working days, in case of downtime or breakdown;
- (f) managing technical issues (such as bug fixing, problem analysis, removal of virus and other malicious codes found in the storage facilities) that may compromise the functioning of the storage service, including offering a helpdesk function in English (telephone or email support available during working hours) related to the storage, and providing service maintenance. Service maintenance shall be communicated in advance to the national administrators;
- (g) ensuring that the Commission's access to the national repository is strictly limited to what is provided for in this Agreement;
- (h) keeping logs of events in the national repository and, where requested, transmitting such information to the national administrator of the national repository concerned;
- (i) creating, as appropriate, a repository for non-confidential information (such as studies) accessible to all national administrators outside the respective national repository.

Article 4

Responsibilities and tasks of the Member State

The Member State is responsible for:

- (a) installing at national level the technical infrastructure (hardware/software) necessary to guarantee secure access to the national repository, including using TestaNG or equivalent secure network as determined by the Commission, and ensuring that all access passes through this secure infrastructure;
- (b) creating an account in the authentication system set up by the Commission in respect of the product category covered by this Agreement as listed in Article 1(1);
- (c) appointing a national administrator with responsibility for each section of the national repository set up in accordance with Article 3(a) and requesting access rights from the Commission for each administrator;
- (d) issuing and monitoring additional access rights to maximum ten subsequent users for each section under the full responsibility of the national administrators;
- (e) ensuring the protection of all data in the national repository, including during the process of extracting reports and disseminating information to the public, unless the responsibility falls under the Commission's responsibilities according to Article 3(d) of this Agreement. The Member State is fully responsible for the protection of trade secrets, confidential and personal data;
- (f) sharing information with other Member States in accordance with Directive 2014/40/EU;
- (g) providing a contact point for manufacturers and importers with a view to answering the queries of submitting parties related to the submissions made to the national repository ;
- (h) any financial damage caused by the disclosure of data in breach of this Agreement, with the exception of damage resulting from a breach by the Commission of its obligations under Article 3 of this Agreement. The Member State shall indemnify the Commission for any damage, expense and loss arising from or linked to any third party claim concerning the use of the service, the use of data stored, the breach of this Agreement or the violation of the applicable law by local administrators or subsequent users, unless the violation is caused by the Commission or as a result of *force majeure*.

Article 5

Data breach management

1. The Member State and the Commission shall immediately inform the other Party and take all necessary actions in the event of any of the following cases:

- (a) where unauthorised access is identified or is suspected to have occurred or the security of the national repository has been violated,
- (b) where the Member State becomes aware that the account information is lost or stolen,
- (c) where the Member State or the Commission become aware of any violation of the Agreement by any user.

Such actions may include revoking access rights to subsequent users.

2. In the cases referred to in paragraph 1, the Member State and the Commission shall fully co-operate and keep the other Party informed of the measures taken.
3. If security risks occur the Commission may immediately suspend the Member State's access right.
4. During the suspension of the account the Member State remains responsible for the protection of the data downloaded.

Article 6

Remuneration

1. The services under this Agreement are provided by the Commission without remuneration, unless there is a change in circumstances, such as the need for a significant increase in storage capacity.
2. In such a case, the Commission shall notify the Member State of the change in circumstances and of the fees to be charged for the services provided. Fees may only commence being charged 15 months following the date of such notification.
3. Following such notification, the Member State may terminate this Agreement in accordance with the procedure laid down in Article 8(4). If the Agreement is not terminated by the Member State, the fees set out in the notification shall begin to be charged following the expiration of the 15 month period referred to in the second paragraph.

Article 7

Transfer of rights

The parties may not assign their rights or obligations under this Agreement to a third party without the written consent of the other Party to this Agreement.

Article 8

Duration of the Agreement and non-compliance with the terms of the Agreement

1. This Agreement shall be effective from the date at which it has been signed by both Parties.
2. The Agreement shall be valid for a period of five years. It shall continue to renew automatically unless it is terminated in accordance with paragraph 3.
3. Except in cases provided for under Article 6, a Party may only terminate this Agreement after the first five years.
4. The terminating Party shall give the other Party at least 12 months' written notice of its decision to terminate the Agreement. The Member State shall communicate without undue delay details of the national storage facilities where the data shall be submitted in future and all necessary specifications linked to the proper functioning of the EU-CEG. The Member State shall also provide all other information necessary in order to allow the Commission to conclude a secure transfer.
5. The Commission may choose to suspend immediately access rights partially or in full where the Member State fail to comply with the terms of this Agreement and the breach of the Agreement does not fall within the responsibility of the Commission.
6. Where a suspected case of non-compliance occurs, which leads to the suspension of the access rights, the Member State shall have the opportunity to present its views, either in writing or in a meeting.
7. Any suspension should be lifted when the parties agree on the resolution of the issue which led to the suspension.

Article 9

Limitation of liability

1. The Commission shall not be liable to the Member State for any damage, compensation or reimbursement arising in connection with:
 - (a) the inability to use the service as a result of any termination or suspension of this Agreement, or any downtime of all or a portion of the service;
 - (b) any unauthorised access, loss or damage related to the data stored, which is not linked to the Commission's responsibility as set out in Article 3(d) of this Agreement.
2. The Commission shall not be liable for any expenditure incurred, investment made or commitment entered into by the Member State in connection with this Agreement.

3. The Commission shall not be liable to the Member State for any damage, delay or failure to perform its obligations which are the result of force majeure or any other causes beyond the reasonable control of the Commission, including systemic electrical, telecommunications or other utilities failures, storms or other elements of nature, or acts of terrorism.

Article 10

Governing law, amendments and dispute resolution

1. This Agreement shall be governed by the law of the European Union and supplemented where necessary by national substantive law of Belgium.
2. Amendments to this Agreement shall only be possible if confirmed in writing by the persons duly authorised to represent the Commission and the Member State.
3. Any dispute between the Parties which cannot be settled amicably shall be brought before the Court of Justice of the European Union in accordance with Article 272 of the Treaty of the Functioning of the European Union.

IN WITNESS WHEREOF the undersigned, being duly authorised, have signed this Agreement.

Done in Brussels, on the 22 of May, 2016

1. For the European Commission: Xavier Prats Monné. Director-General for Health and Food Safety

2. For the Member State: Mrs. Mariya Kasheva, Director of Tobacco and Tobacco Products Institute