

EUROPEAN COMMISSION

> Brussels, 15.12.2017 C(2017) 8429 final

ANNEX 1

ANNEX

to the

Commission Implementing Regulation (EU) .../...

on technical standards for the establishment and operation of a traceability system for tobacco products

ANNEX I

SELECTION PROCEDURE FOR INDEPENDENT THIRD PARTY PROVIDERS OF REPOSITORY SYSTEMS

PART A

The following procedures shall apply to the selection of an independent third party provider operating a primary repository:

- 1. Each manufacturer and importer of cigarettes and roll-your-own tobacco shall notify to the Commission, no later than two months following the entry into force of Commission Delegated Regulation (EU) \dots/\dots^1 :
 - (a) the identity of the third party that it proposes to appoint to operate a primary repository (the "proposed provider"), and
 - (b) a draft data storage contract containing the key elements laid down in the Delegated Regulation for approval by the Commission.
- 2. The notification shall be accompanied by:
 - (a) the written declaration of technical and operational expertise, referred to in Article 4 of Delegated Regulation (EU) .../...,
 - (b) the written declaration of legal and financial independence, referred to in Article 8 of Delegated Regulation (EU) .../..., and
 - (c) a table setting out the correspondence between the contractual clauses and the requirements laid down in Delegated Regulation (EU) .../....
- 3. The Commission shall, within three months of the date of receiving the notification, and on the basis of an examination of the suitability of the proposed provider, in particular, as regards its independence and technical capacities as referred to in Article 15(8) of Directive 2014/40/EU, approve or reject the proposed provider and the draft contract. In the absence of a reply by the Commission within that timeframe, the provider and the draft contract shall be deemed to be approved.
- 4. Where the Commission does not approve the proposed provider or the draft contract, or where it considers that the contract does not incorporate the key elements laid down in Delegated Regulation (EU) .../..., the manufacturer or importer concerned shall, within one month of being informed by the Commission, propose an alternative provider and/or make necessary amendments to the draft contract for further consideration by the Commission.
- 5. Once the proposed provider and the draft contract have been approved, the manufacturers and importers shall, within two weeks of such approval, provide in electronic format:
 - (a) a copy of the contract signed by both parties, and
 - (b) the declarations required to be provided as part of the contract under Articles 4 and 8 of Delegated Regulation (EU) .../....
- 6. Manufacturers and importers of tobacco products other than cigarettes and roll-your-own tobacco shall notify to the Commission, by 31 December 2022, the identity of the proposed provider, a draft

¹ [Commission Delegated Regulation (EU) .../... of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products – C(2017) 8415 final (OJ L [...], p. [...])].

data storage contract containing the key elements laid down in Delegated Regulation (EU) .../... for approval by the Commission, and the additional documentation referred to in paragraph 2.

- 7. The provider appointed to operate the primary repository shall only integrate its repository into the traceability system following the conclusion of the approved contract.
- 8. A list of notified and approved third parties shall be made publicly available by the Commission on a website.
- 9. Any amendment to the key elements of the contract, as defined in Delegated Regulation (EU) .../..., shall be subject to approval by the Commission. Any other amendment to the contract shall require prior communication to the Commission.

PART B

The following procedure shall apply to the selection of an independent third party operating the secondary repository system:

- 1. The Commission shall appoint, from amongst the providers of the primary repositories who have been approved in accordance with Part A within six months following the entry into force of Delegated Regulation (EU) .../..., a provider tasked with operating the secondary repository ("the operator of the secondary repository") for the purpose of carrying out the services specified in Chapter V of this Regulation.
- 2. The appointment of the operator of the secondary repository shall be based on an assessment of objective criteria and take place no later than eight months following the entry into force of Delegated Regulation (EU) .../....
- 3. The result of the appointment of the operator of the secondary repository shall be made publicly available by the Commission on a website.
- 4. Each primary repository provider appointed in accordance with Part A shall enter into an individual contract with the provider appointed to operate the secondary repository for the purpose of carrying out the services specified in Chapter V of this Regulation.
- 5. The contracts shall be signed and submitted to the Commission within one month from the date of the appointment.

PART C

The following requirements shall apply in addition to the selection procedures outlined in Parts A and B:

- 1. Where the contractual relationship between a manufacturer and importer and the provider of a primary repository is terminated, or expected to be terminated, by any of the parties to the contract, for any reason, including the failure to comply with the criteria for independence laid down in Article 35, the manufacturer or importer shall immediately inform the Commission of such termination, or expected termination, and as soon as it is known, the date of the notification of termination and the date at which the termination is to take effect. The manufacturer or importer shall propose and notify to the Commission a replacement provider as soon as practicable, and at the latest, three months prior to the termination date of the existing contract. The appointment of the replacement provider shall take place in accordance with paragraphs 2 to 7 of Part A.
- 2. In the event that the operator of the secondary repository gives notice of its intention to cease operating that repository in accordance with the contracts entered into pursuant to paragraph 4 of

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Part B, it shall immediately inform the Commission thereof and of the date at which the termination is to take effect.

- 3. Where the finding referred to in paragraph 1 applies to the provider who has been appointed to operate the secondary repository, the contracts for the operation of the secondary repository entered into pursuant to paragraph 4 of Part B shall, in turn, be terminated by the parties.
- 4. In cases referred to in paragraphs 2 and 3, the Commission shall appoint a replacement operator as soon as practicable, and at the latest, three months prior to the termination date of the existing contract.