Commission Delegated Regulation (EU) 2018/573 of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2018/573

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on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 15(12) thereof,

Whereas:

(1) Article 15(8) of Directive 2014/40/EU requires each manufacturer and importer, as part of the traceability system for tobacco products, further specified in Commission Implementing Regulation (EU) 2018/574[(2)], to conclude a contract with an independent third-party provider for the purpose of hosting information related to its tobacco products. Article 15(12) of Directive 2014/40/EU empowers the Commission to define the key elements of those contracts.

(2) To ensure the effective functioning of the traceability system for tobacco products in general and the interoperability of the repositories system in particular, it is appropriate to lay down the key elements of the data storage contracts, to include specifications relating to the operability, availability and performance of the services to be provided by data storage providers. The effective and continuous functioning of the traceability system and the data storage system contained therein makes it necessary that clear requirements on data portability are put in place by providers for cases where a manufacturer or importer decides to change its provider. For that reason, the contracts should include provisions requiring the use of technology that is readily available on the market and commonly used in the sector to guarantee an effective and uninterrupted data transfer between current and new providers.

(3) In order to ensure the necessary level of flexibility, it should be possible to request the data storage provider to carry out, against a fee, ancillary technical services connected with the operation of the primary repository such as the expansion of the operational functionality of user interfaces, provided that the additional services contribute to the proper functioning of the repositories system and do not violate any of the requirements

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laid down in Implementing Regulation (EU) 2018/574. Therefore, the contract should provide for such an option.

(4) To safeguard the independent operation of the traceability system at all times, the Commission should be able to revoke the approval of an already contracted data storage provider where an assessment or reassessment of the technical capacity or independence of the provider results in an adverse finding as regards its suitability.

(5) In order to ensure the effective organisation of the day-to-day functioning of the system, providers of primary repositories should cooperate with one another, as well as with the competent authorities of Member States and the Commission.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation sets out key elements to be included in the data storage contracts referred to in Article 15(8) of Directive 2014/40/EU.

Article 2

Definitions

For the purpose of this Regulation, in addition to the definitions laid down in Directive 2014/40/EU and Implementing Regulation (EU) 2018/574, the following definitions shall apply:

(1) ‘contract’ means a contractual agreement between a manufacturer or importer of tobacco products and a provider of data storage systems in accordance with Article 15(8) of Directive 2014/40/EU and Implementing Regulation (EU) 2018/574;

(2) ‘provider’ means any legal person contracted by a manufacturer or importer of tobacco products for the purpose of establishing and operating its primary repository and the related services;

(3) ‘data portability’ means the ability to move data among different repositories, by the use of technology that is readily available on the market and commonly used in the sector.

Article 3

Key responsibilities under the contract

1 The contract shall specify the key services to be rendered by the provider, which shall include:

(1) the establishment and operation of a primary repository in accordance with Article 26 of Implementing Regulation (EU) 2018/574;

(2) in the case the operator of the primary repository is appointed as provider of the secondary repository, the establishment and operation of the secondary repository and

the router, in accordance with Articles 27, 28 and 29 of Implementing Regulation (EU) 2018/574;

(3) the provision, upon request, of other ancillary technical services connected with the operation of the primary repository that contribute to the proper functioning of the repositories system.

2 In defining the key services referred to in points (1) and (2) of paragraph 1, the contract shall contain specifications relating to the operability, availability and performance of the services meeting the minimum requirements specified in this Regulation and laid down in Chapter V of Implementing Regulation (EU) 2018/574.

Article 4

Technical expertise

The contract shall require providers to issue to the manufacturer or importer a written declaration that they hold, or have at their disposal, the technical and operational expertise necessary to carry out the services referred to in Article 3 and to comply with the requirements laid down in Chapter V of Implementing Regulation (EU) 2018/574.

Article 5

Availability of the primary repository

1 The contract shall specify a guaranteed monthly uptime and availability of 99,5 % for the primary repository.

2 The contract shall require that appropriate back-up mechanisms are put in place by the provider to prevent any loss of data that is stored, received or transferred at the time the primary repository becomes unavailable.

Article 6

Access rights

The contract shall specify the requirements for physical and virtual access to be granted, at server and database level, to national administrators of Member States, the Commission, and appointed external auditors to the primary repository, in accordance with Article 25 of Implementing Regulation (EU) 2018/574.

Article 7

Sub-contracting

1 Where the contract specifies that the provider may subcontract certain obligations under the contract, it shall contain a provision clarifying that the subcontract does not affect the primary responsibility of the provider for the performance of the contract.

2 The contract shall further require the provider:

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a to ensure that the proposed subcontractor has the necessary technical expertise and meets the requirements of independence laid down in Article 35 of Implementing Regulation (EU) 2018/574.

b to submit to the Commission a copy of the declaration referred to in Article 8 of this Regulation signed by the respective sub-contractor(s).

Article 8

Legal and financial independence

The contract shall require providers and, where applicable, their sub-contractors, to issue to the manufacturer or importer, together with the data storage contract, a written declaration that they comply with the requirements for legal and financial independence as laid down in Article 35 of Implementing Regulation (EU) 2018/574.

Article 9

Data protection and confidentiality

1 The contract shall specify that the provider shall put in place all appropriate measures necessary to ensure the confidentiality, integrity and availability of all data stored in the performance of the contract. Such measures shall include administrative, technical and physical safety and security controls.

2 The contract shall require that personal data handled under the contract are processed in accordance with Directive 95/46/EC of the European Parliament and of the Council[(3)].

Article 10

Information security management

The contract shall require providers to declare that the primary repository and, where applicable, the second repository, is managed in accordance with internationally recognised information security management standards. Providers certified to ISO/IEC 27001:2013 shall be presumed to meet those standards.

Article 11

Costs

The contract shall require the costs charged by providers to manufacturers or importers in accordance with Article 30 of Implementing Regulation (EU) 2018/574 to be fair, reasonable, and proportionate to:

(a) the services rendered; and

(b) the number of unique identifiers requested over a given period of time by the manufacturer or importer concerned.