

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

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)

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

Changes to legislation: There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/573, Introductory Text. (See end of Document for details)

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:

Changes to legislation: There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/573, Introductory Text. (See end of Document for details)

- (1) [OJ L 127, 29.4.2014, p. 1.](#)
- (2) Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (see page 7 of this Official Journal).

Changes to legislation:

There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/573, Introductory Text.