



Brussels, 27.9.2018
C(2018) 6211 final

COMMISSION DECISION

of 27.9.2018

concerning the approval of a proposed data storage provider and the related data storage contract to be concluded as part of the traceability system for tobacco products

(Only the English text is authentic)

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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/EC¹, and in particular Article 15(8) thereof,

Whereas:

- (1) Directive 2014/40/EU, Commission Delegated Regulation (EU) 2018/573² and Commission Implementing Regulation (EU) 2018/574³ set out the legal framework for the establishment of a Union-wide traceability system for tobacco products.
- (2) Article 15(8) of Directive 2014/40/EU requires Member States to ensure that manufacturers and importers of tobacco products conclude data storage contracts with independent third parties for the purpose of hosting the data storage facilities for all relevant data submitted to the traceability system. The data storage contract and the suitability of the third party, in particular its independence and technical capacities, must first be approved by the Commission. Annex I to Implementing Regulation (EU) 2018/574 lays down the procedural rules for that approval process, including the documents required to be submitted and the timeframe in which the Commission must examine those documents.
- (3) On 3 July 2018, TWIST N.V. notified the Commission about the proposed conclusion of a draft data storage contract as well as the identity of the third party provider that it proposes to operate a primary repository, in accordance with Article 26 and Part A of Annex I to Implementing Regulation (EU) 2018/574.
- (4) As provided for in point 2 of Part A of Annex I to Implementing Regulation (EU) 2018/574, the notification was accompanied by written declarations of technical and operational expertise, and of legal and financial independence, and a table setting out the correspondence between the contractual clauses and the requirements laid down in Delegated Regulation (EU) 2018/573.

¹ OJ L 127, 29.4.2014, p. 1.

² Commission Delegated Regulation (EU) 2018/573 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products (OJ L 96, 16.4.2018, p. 1).

³ Commission Implementing Regulation (EU) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products (OJ L 96, 16.4.2018, p. 7).

- (5) When assessing the suitability of the proposed third party provider, the Commission examined whether the requirements concerning the independence of the proposed third party provider, as well as its technical and operational capacities, are satisfied. The assessment was based on the written declarations, as well as on other information available to the Commission at the time of the examination.
- (6) When assessing the draft data storage contract, the Commission examined the completeness of the contract to ensure that it contains the key elements required under Delegated Regulation (EU) 2018/573. Furthermore, the Commission examined whether the draft contract complies with the general rules related to data storage facilities, notably the restrictions related to access to the stored data, as laid down in Article 15(8) of Directive 2014/40/EU.
- (7) Based on its examination, the Commission concludes that the proposed third party provider and the related draft data storage contract satisfy the requirements set out in Directive 2014/40/EU, Delegated Regulation (EU) 2018/573 and Implementing Regulation (EU) 2018/574.
- (8) It is therefore appropriate for the Commission to approve the third party provider proposed as the primary repository and the draft data storage contract.
- (9) Pursuant to Article 35(5) of Implementing Regulation (EU) 2018/574, any change in circumstances capable of affecting the independence of the proposed third party provider, and, where applicable its subcontractors, that subsists for two consecutive calendar years, is to be communicated to the Commission without delay.
- (10) Pursuant to the second subparagraph of Article 15(8) of Directive 2014/40/EU, the activities of the third party provider are to be monitored by an external auditor. In particular, the external auditor must submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to the access to the stored data.
- (11) Any amendments to the key elements of the notified data storage contract, as defined in Delegated Regulation (EU) 2018/573, are subject to approval by the Commission.
- (12) In accordance with point 5 of Part A of Annex I to Implementing Regulation (EU) 2018/574, no later than two weeks from the date of notification of the Commission's decision to approve the proposed third party provider and the related draft data storage contract, a copy of the contract signed by both parties, as well as the written declarations to be provided as part of the contract, should be submitted to the Commission in electronic format,

HAS ADOPTED THIS DECISION:

Article 1

The draft data storage contract notified by TWIST N.V. on 3 July 2018, and the third party provider proposed to operate the primary repository, are approved.

Article 2

In accordance with point 5 of Part A of Annex I to Implementing Regulation (EU) 2018/574, a copy of the contract signed by both parties, and the written declarations to be provided as part of the contract, shall be submitted to the Commission in electronic format within two weeks from the date of notification of this Decision.

Article 3

This Decision is addressed to TWIST N.V., Vantegemstraat 7, 9230 Wetteren, Belgium.

Done at Brussels, 27.9.2018

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

