

Appendix 1: Key features of the technical specifications for the EU T&T system

Feature	Description
Unique Identification Markings (UIDs)	The ITP defines Unique Identification Markings (UIDs) as non-removable identification markings which are affixed to or form part of unit packs. ¹ Under the EU system UIDs will take the form of alphanumeric codes. The key task of generating the UIDs at unit packet level is given to an “independent third party” appointed by each Member State. Manufacturers and importers are tasked with verifying the UIDs “so as to ensure their correct application and readability”. ³
Security Features	Under International ISO standards, authentication is defined as the act of establishing whether a material good is genuine or not. ⁴ Under the EU regulations, security features must consist of at least 5 different authentication elements, including at least 1 overt feature which can be seen by the naked eye (eg. hologram, patterns, colour shifting inks), 1 semi-covert (eg. UV dull paper, microprint) and a covert (eg. magnetic elements, molecular tags) element. ³ In order to provide an additional safeguard to the security features, the EU regulation requires that a minimum of 1 authentication element selected by Member States be sourced from an independent party, with the aim of “reducing the potential for attacks perpetrated by persons or entities that are directly or indirectly connected with the producer or originator of authentication elements used to develop the security features”. ⁵
Anti-tampering devices	To safeguard the system from industry interference, ‘independent’ third-parties are tasked with supplying anti-tampering devices to be installed on devices used for verification purposes. These ensure the integrity of the system by monitoring tobacco production lines, verifying if UIDs have been applied as required. Neither the TPD ⁶ nor the EU T&T implementation regulations ^{3,7,8} specify clear requirements for the anti-tampering devices and there are no similar controls for the supply or application of security features.
Data repositories	<p>Manufacturers and importers of tobacco products are responsible for concluding data storage contracts with an “independent third-party provider” to operate a primary repository which will store traceability data relating to the products of that manufacturer/importer. On 10 October 2018, the European Commission released a list of organisations that it had approved as independent third parties, suitable to provide primary data repositories:²</p> <p>Atos AG Atos Information Technology GmbH Atos IT Solutions and Services A/S Atos Polska S.A., Dentsu Aegis Network Switzerland AG IBM United Kingdom Limited Movilizer GmbH Zetes S.A.</p> <p>In addition to these primary repositories, a single secondary repository will contain a copy of all data stored in every primary repository aimed at giving authorities an overview of the functioning of the T&T system.³ On 21 December 2018, the EC appointed Dentsu Aegis Network Switzerland AG as the provider that will operate the secondary repository.⁹</p> <p>In the delegated regulation, the European Commission defines the key elements of the contracts between independent third-parties and tobacco manufacturers for the hosting of information related to each tobacco manufacturer’s products. These include that contracts must include terms allowing European Commission-approved external auditors to carry out announced and unannounced audits of</p>

	data repositories, that repositories are managed in accordance with international standards, and that the European Commission should be able to revoke the approval of an already contracted data storage provider should it no longer be deemed suitable either due to technical capacity or insufficient independence. ⁷
Independence criteria	the European Commission uses three criteria to establish the independence of a third-party (including the UID issuer and data storage providers) involved in the T&T system from the tobacco industry: <ul style="list-style-type: none"> • legal, organisational and decision-making independence. • financial independence (that less than 10% of a third-party's annual worldwide turnover comes "from goods and services supplied to the tobacco sector over the past two calendar years".³ The threshold then becomes 20% for each subsequent year.⁸ No explanations is provided as to why these particular thresholds were chosen). • absence of conflicts of interests, namely that directors and other governing individuals have not participated in tobacco industry company structures in the last 5 years and shall act independently from any financial or other links to the tobacco industry such as tobacco stocks or private pension programmes.⁸
Auditing of independence	The procedures governing the appointment of the UID issuers and other providers and their compliance with the EU's independence criteria will undergo "periodic review by the European Commission" ⁸ and the EC "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." ³ No specific provisions have been set out in terms of how the auditing (both initial and ongoing) will be undertaken and what documents or other criteria would be the basis of such review by the European Commission.

[1] World Health Organization. *Protocol to Eliminate Illicit Trade in Tobacco Products*. 2013. Available: http://www.who.int/fctc/protocol/illicit_trade/protocol-publication/en/ (accessed 21 Jan 2018).

[2] European Commission. *EU system of traceability for tobacco products - List of approved providers of primary repositories* -. 10 October 2018. Available: https://ec.europa.eu/health/sites/health/files/tobacco/docs/primaryrepositories_approvedproviders_en.pdf (accessed 20 February 2019).

[3] European Commission. Commission Implementing Regulation (EU) 2018/574 of December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products. *Official Journal of the European Union* 16 April 2018.

[4] Swedish standards Institute. *International Standard: Performance criteria for authentication solutions used to combat counterfeiting of material goods*. 2012. Available: <https://www.sis.se/api/document/preview/914767/> (accessed 29 March 2019).

[5] European Parliament. Resolution on the Commission communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption (COM(96) 0609 C4-0014/97) on 18.12.1997. *Official Journal of the European Communities*; **C 014** , 19/01/1998 **P. 0197** 99-102.

- [6] European Commission. *Revision of the Tobacco Products Directive 2014/40/EU*. 2014. Available: https://ec.europa.eu/health/tobacco/products/revision_en (accessed 25 September 2017).
- [7] European Commission. 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. *Official Journal of the European Union* 16 April 2018.
- [8] European Commission. Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products *Official Journal of the European Union* 16 April 2018.
- [9] European Commission. *Systems for tobacco traceability and security features*. undated. Available: https://ec.europa.eu/health/tobacco/tracking_tracing_system_en (accessed 20 February 2019).