



Why the EU tracking and tracing system works only for the EU

Key Recommendations

- Parties to the Illicit Trade Protocol should not choose a tracking and tracing (T&T) solution which, as in the case of the EU TPD, allows for the delegation of obligations to tobacco companies, such as the choice of the data storage providers. This would be a breach of the independence requirements of the ITP.
- Parties to the ITP should require that providers of data storage services and generators of unique identifiers (UIs) should not be selected by the tobacco industry itself and furthermore have no links to the development of the tobacco industry's track and trace solution(s).
- Parties to the ITP should use authentication elements and anti-tampering devices (such as digitally signed alphanumeric codes¹, security ink as found in tax stamps). Digital signatures prevent third parties from generating their own codes. Security features prevent the copying of the UI.
- Parties to the ITP should ensure that all authentication elements are supplied, installed and controlled by authorities independent from the tobacco companies.
- Parties to the ITP should require that the Unique Identifier include only the elements listed in the ITP (date and place of manufacturing, manufacturing facility, product description and where available intended market of retail sale), not the longer list required by the EU.
- Parties to the ITP should give serious consideration as to whether a time stamp is necessary

Why this is important

This briefing examines the European Union's (EU) tracking and tracing (T&T) system which came into force on 20 May 2019. It consists of two parts: part A outlines a series of considerations for policy makers; part B provides detailed explanations about technical aspects that need to be taken into account.

A. MAIN CONSIDERATIONS FOR POLICY MAKERS

Other Parties to the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) may look to this system as a model and even consider copying or importing it. However tempting this may be, Parties need to be aware of certain special European circumstances and shortcomings in the EU system. This

¹ Digital signatures are created using a public-key signature algorithm such as the RSA public-key cipher. A public-key algorithm actually uses two different keys: the public key and the private key (called a key pair). The private key is known only to its owner, while the public key can be available to anyone. Public-key algorithms are designed so that if one key is used for encryption, the other is necessary for decryption (see: [https://docs.microsoft.com/en-us/previous-versions/windows/internet-explorer/ie-developer/platform-apis/ms537361\(v=vs.85\)](https://docs.microsoft.com/en-us/previous-versions/windows/internet-explorer/ie-developer/platform-apis/ms537361(v=vs.85))).

briefing sets out to explain where the EU system does and does not fulfil the requirements of the ITP. It also puts forward recommendations for ITP Parties on the process of developing and implementing a tracking and tracing (T&T) system as part of the Protocol obligations and for members of the Working Group (WG) on Article 8 of the ITP. The WG on Article 8 was established by the first Meeting of the Parties (MOP) to the Protocol in October 2018 in Geneva. It is due to start its work towards the end of 2019. ITP Parties are encouraged to await the results of this WG rather than risk adopting a system that does not meet their needs and would allow for the tobacco industry and its partners to play an active rather than a compliant role.

The EU itself, as well as 15 of 28 EU Member States (MS), had become Parties to the ITP at the time of writing. However, since the EU's own legislation has now come into force, all its MS are required to implement an EU-wide tracking and tracing system for tobacco products as stipulated by the [Tobacco Products Directive \(2014/40/EU\)](#) (TPD).

This briefing highlights key features of the EU's T&T system, including its strengths and weaknesses. Generally speaking, this first regional T&T may produce results in a European context but is likely to fail if adopted by any other ITP Party. The main reasons for this conclusion is the complexity of the system itself (which has to incorporate several layers of the EU's multi-layered government system), its vulnerability to cloning (falsification of security markers on packages, cartons and/or master cases) by the tobacco industry and its inadequate independence criteria for actors with ties to the tobacco industry, in breach of the obligations set out in Article 8 of the ITP and Article 5.3 FCTC.

There is a major risk that the EU tracking and tracing system may be promoted to other countries or regional organisations. Versions of the EU regulation (some of which, for example, exclude the independence criteria) were promoted to ITP Parties and had support from the tobacco industry². That is precisely the strategy developed by the tobacco industry to promote its own tracking and tracing solution and to preserve its control on the illicit trade. Parties to the ITP are urged to consider following the recommendations above.

Background and timelines

- **2006: The Conference of the Parties (COP) to the FCTC decided to negotiate a Protocol in order to tackle the illicit trade in tobacco products because of the major role played by the tobacco industry in this criminal activity**
- **2012: Adoption of the Protocol to Eliminate Illicit Trade in Tobacco Products during the FCTC COP5 session in Seoul;**
- **2014: Adoption of the European Tobacco Products Directive (EU TPD) including provisions for a tracking and tracing system and security features which do not comply with the Protocol; the EU agreed on a five year deadline to operationalize a tracking and tracing system for its 28 Member States;**
- **2016, June: European Commission announces decision not to renew anti-illicit trade agreement with Philip Morris International (PMI);**
- **2016: Ratification of the Protocol by the European Union;**
- **2018, September: Once the 40th country became a Party, the Protocol came into force; the EU and 15 EU Member States (as of July 2019) are Parties to the ITP.**
- **2018, October: The First Meeting of the Parties to the Protocol (MOP1) took place at UN level.**

²Tabac : les fumeuses manœuvres de Philip Morris pour contrôler la traçabilité des cigarettes, Journal du Dimanche, 14 July 2018, <https://www.lejdd.fr/Societe/tabac-les-fumeuses-manoevres-de-philip-morris-pour-controler-la-tracabilite-des-cigarettes-3710306>

B. KEY TECHNICAL ASPECTS

1) What is the EU tracking and tracing system for tobacco products?

The [EU Tobacco Products Directive \(2014/40/EU\)](#) requires the establishment of an EU-wide tracking and tracing system for the legal supply chain of tobacco products (Article 15 TPD), as well as a system of security features to enable authorities and citizens to verify the authenticity of a tobacco product (Article 16 TPD). Both the traceability system and the security features must be in place **by 20 May 2019** for cigarettes and roll-your-own tobacco, and **by 20 May 2024**, for all other tobacco products (such as cigars, cigarillos and smokeless tobacco products).^{3 4}

Elements of the EU tracking and tracing system

a) Unique identifier⁵

Each Member State must

- Appoint an 'ID issuer' to be responsible for generating and issuing Unique Identifier (UI) codes to be applied to unit packets, and
- Ensure the ID issuer's independence from the tobacco industry.⁶

Each unit packet manufactured in or imported into the EU (included products intended for export) must be marked with a unit level UI which must consist of the UI issuer identification code, an unpredictable serial number, and a product code (which includes the place of manufacturing; the manufacturing facility; the machine used to manufacture the tobacco products; the product description; the intended market of retail sale; the intended shipment route; and where applicable, and the importer).

The ID issuers must generate UIs, composed of numbers and/or letters, for unit packets, and where requested, aggregated packaging.

ID issuers also issue identifier codes for all relevant economic operators (including retailers), facilities and machines, so they may be easily identified under the system.

b) Data storage⁷

All movements along the supply chain are recorded up to the first retail outlet. Each manufacturer and importer of tobacco products are required to conclude a contract with a data storage provider (a 'primary' repository), to host the traceability data exclusively related to their products.

³ European Parliament, Council of the European Union. *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*. 2014. Available : <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=en>

⁴ European Commission. *Tobacco track and trace systems: Questions and Answers*. 25 December 2017. Available: http://europa.eu/rapid/press-release_MEMO-17-5270_en.pdf

⁵ European Commission. *Commission Implementing Regulation (EU) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products*. 15 December 2017. Available : <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0574&from=GA>

⁶ A list of already appointed ID issuers can be found in the subgroup on traceability and security features' reports. European Commission. *Meeting of the subgroup on traceability and security features - summary record*-. 12 March 2019. Available: https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20190312_sr_en.pdf

⁷ European Commission. *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*. 15 December 2017. Available : <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0573&from=EN>

Repositories are selected and paid for by the manufacturers but must be approved by the European Commission.⁸

Among the selected primary repositories, the European Commission has selected one as the secondary repository⁹ which will store a copy of all traceability data from the primary repositories for all the products within the EU. Member States (MS) will have to access via the secondary repository which provides an overview of all product movements.

c) Security features¹⁰

Security features are designed to enable authorities and citizens to verify the authenticity of a tobacco product (but not the authenticity of the UI). The security features must be applied to packs by means of printing and/or affixing. To ensure a high level of security, they must be composed of five types of 'authentication elements' of which at least one must be provided by an independent third party provider.

- At least one authentication element must be visible by the human eye –or 'overt'.
- At least one authentication element must be invisible and only detectable with purpose-built tools or professional lab equipment –or 'covert'.
- There must also be at least one 'semi-covert' feature, which is invisible but can be detected with non-specialist equipment such as a UV torch or a special pen.

d) Anti-tampering devices

Anti-tampering devices must be fitted to tobacco production lines to check the correct application and readability of the UIs and notify authorities in real time of any deviation. They must be supplied and installed by an independent third party.

e) Audit

Manufacturers and importers are required to choose and pay an external auditor, which must be approved by the EU, to monitor the data storage and submit annual reports to the MS.

f) Independence criteria

The EU adopted criteria for assessing “independence” in the context of the tracking and tracing system operators (UI issuers, data storage providers, security feature providers, anti-tampering device providers). These criteria include:

- Legal, organisational and decisional independence from the tobacco industry (direct or indirect control, including minority shareholding);
- Financial independence (less than 10% turnover during the last 2 calendar years from tobacco industry before signing a contract and less than 20% before that);
- The absence of conflict of interest in the management of these companies, including direct stockholding, not having worked with tobacco industry in the last five years, etc.

⁸ The list of approved primary repositories has been published by the Commission in October 2018. 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

⁹ Dentsu Aegis Network Switzerland AG has been nominated as the secondary repository on 21 December 2018. https://ec.europa.eu/health/tobacco/tracking_tracing_system_en

¹⁰ European Commission. *Commission Implementing Decision (EU) 2018/576 on technical standards for security features applied to tobacco products*. 15 December 2017. Available : <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0576&from=EN>

2) Strengths of the EU system

- From 20 May 2019, the European Union tracking and tracing system for tobacco products down to unit packet level will be operational and apply to 28 countries and cover all economic operators in the supply chain, up to the first retail outlet. This is broadly in line with the Article 8.10 of the ITP, defining the scope of the system (*“Each Party shall require the further development and expansion of the scope of the applicable tracking and tracing system up to the point that all duties, relevant taxes and where appropriate, other obligations have been discharged at the point of manufacture, import or release from customs or excise control.”*).
- Unique identifiers will be generated in advance by independent companies and not by the tobacco companies.

All movements of tobacco products in the EU will be recorded and all economic operators (including retailers), all facilities and production lines will receive an identification code and will be identified.

3) Weaknesses of the EU system and recommendations to Parties to the Protocol about how these can be eliminated in future tracking and tracing systems

- The EU system is based on a complex system with a mix of responsibilities for tobacco companies, independent third parties, EU Commission and EU Member States. The EU system has a major built-in flaw: it allows manufacturers and importers to choose data storage providers and auditors. This delegation of tasks to the tobacco industry is in conflict with Article 8.12 of the ITP (obligations assigned to a Party shall not be performed by or delegated to the tobacco industry). **Parties to the ITP therefore should not choose a solution which, as the EU TPD does, allows for the delegation of obligations to tobacco companies, in breach of the independence requirements of the ITP.**
- The EU system does not provide sufficient control by independent third parties when the unique identifiers are applied at the time of manufacturing. Tobacco producers could exploit this weakness by cloning or not affixing a unique identifier to some of the cigarette packets they produce and let these leak into the black market.
- The EU independence rules for third parties and data storage companies defined in the EU secondary legislation can easily be circumvented, as evidenced by the appointment of several data storage providers with historical links to tobacco companies¹¹. At EU level, the independence rules should be strengthened; in the meantime, **Parties to the ITP should require that providers of data storage services and generators of unique identifiers have not had links to the development of the tobacco industry’s track and trace solution(s)** and should ensure that such entities have not provided the following services to the tobacco industry for at least 5 years:
 - Systems integration related to track and trace or supply chain event management;
 - Provision of production control/anti-tampering devices or monitoring;
 - Data storage or related services;
 - Software development related to the generation of Unique Identifier Codes; and,

¹¹ Gilmore AB, Gallagher AWA, and Rowell A. *Tobacco industry’s elaborate attempts to control a global track and trace system and fundamentally undermine the Illicit Trade Protocol*. Tob Control 2019;28:127–140. doi:10.1136/tobaccocontrol-2017-054191. Available at: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/28/2/127.full.pdf>

- Software development related to business intelligence, reporting or queries in connection with tobacco industry track and trace systems.
- The EU system requires the security feature to be used to authenticate the pack, but not necessarily the UI. Article 8.3 of the ITP requires a “*unique, **secure**, and non-removable identification marking*”. **Parties to the ITP should use authentication elements to secure the unique identifiers and to protect the unique identifiers against copying**, both for tobacco products consumed domestically and those which are exported.
 - The EU does not require fully independent security features. Although under the regulation all the security features can be independently sourced, it only requires that 1 out of 5 elements must be sourced by an independent provider **Parties to the ITP should ensure that all authentication elements are supplied by companies independent from the tobacco industry** in order to ensure the industry does not game the system as it has done on multiple occasions.
 - The EU list of elements to be included in the UI is longer than the one required by the Protocol. While this may seem like an additional level of control, it makes the implementation of the traceability system unnecessarily complex and could hinder implementation particularly in middle and low income countries. Furthermore, the required data must be gathered from multiple sources and requires input from the tobacco industry. **Parties to the ITP should require that the UI includes only the elements listed in the ITP (date and place of manufacturing, manufacturing facility, product description and where available intended market of retail sale), not the longer list required by the EU.** The EU legislation requires a time stamp at the time of manufacturing. This might seem like a good idea, but requires an additional label and is an additional problem when a tax stamp is used for traceability purposes. Tax stamps are generated in advance of the manufacturing and e tax stamps. None of the EU countries have used tax stamps for traceability purposes. **Parties to the ITP should question whether a time stamp is necessary** and whether it can be replaced by the use of a camera and/or an anti-tampering device which records the time of production and controls the correct applications of labels or stamps on the packs. Parties should make the time recording easily accessible to law enforcement officials when tobacco products are seized. In 2023, when the ITP system should be operational, we expect that smart phones or other devices should facilitate the easy access of these data when needed.