

## Tracking and Tracing of Tobacco Products: Defining Roles and Responsibilities in Compliance with the FCTC Protocol

**This document analyses the key technical requirements related to track and trace under the WHO FCTC and Article 8 of its Protocol to Eliminate Illicit Trade in Tobacco products, specifically taking into account the requirement to interact with the tobacco industry itself only where ‘strictly necessary’.**

**Analysing the different stages of a full track and trace system, the document identifies which processes in real life need the tobacco industry’s active involvement to a greater or lesser extent. This is the case in six of the 14 separate processes identified, principally in the warehousing and distribution phase.**

**Finally, the document draws a comparison with what has been promulgated in the EU Tobacco Products Directive. The Directive falls short of both security industry best practice and the WHO standards, allowing the tobacco industry and its allies to perform tasks which could and should be done independently.**

### 1. INTRODUCTION

This document has been written by the International Tax Stamp Association (ITSA) as a contribution to the work being carried out on implementing a tobacco track and trace system compliant with the WHO Framework Convention on Tobacco Control (FCTC) and its Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol). The Protocol is an international treaty that entered into force on 25 September 2018 and that requires Parties to establish by 2023 a tracking and tracing system, controlled by the Parties, for all tobacco products manufactured in or imported onto their territory, with the aim of establishing a global tracking and tracing regime.

Technical requirements for the establishment of the system are set out in Article 8 of the Protocol, which specifies unique, secure and non-removable identification markings (UIMs) that must be affixed to or form part of all products, as well as a list of data elements that must be captured and managed in the tracking and tracing system.

Governance requirements to determine roles and responsibilities for the establishment of the system are articulated both in the FCTC and the Protocol and are driven primarily by the need to prevent conflicts of interest and to reduce the risk of fraud by the tobacco industry.

FCTC Article 5.3 requires Parties to protect tobacco control policies from commercial and other vested interests of the tobacco industry. Protocol Articles 8.2 and 8.12 require the tracking and tracing system to be controlled by the Parties and state that obligations assigned to a Party ‘shall not be performed by or delegated to the tobacco industry’. Finally, Article 8.13 of the Protocol requires each Party to ensure that ‘its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary’.

In order to establish a system that complies fully with the defined requirements, a competent government authority ('Authority') representing a Party should develop (internally, or by contracting technology suppliers that are fully independent from the tobacco industry) and execute in full independence all technical activities required by Article 8 of the Protocol, without any reliance on the tobacco industry.

In practice, this may be a challenge, since track and trace equipment needs to be integrated into production lines and some of the data, such as shipment data and invoicing for instance, can only be supplied by the tobacco industry itself. For this reason, some degree of collaboration and interaction with the tobacco industry must be tolerated.

The purpose of this document is to provide technical insights into the different operational activities that need to be carried out, and to distinguish those where collaboration and interaction with the tobacco industry is strictly necessary and those where it is not.

## **2. TRACKING AND TRACING ACTIVITIES**

Articles 8.4.1 and 8.4.2. provide a list of data elements that compose UIMs and that must be captured and managed in the tracking and tracing system. These include: (a) date and location of manufacture; (b) manufacturing facility; (c) machine used to manufacture tobacco products; (d) production shift or time of manufacture; (e) the name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer; (f) the intended market of retail sale; (g) product description; (h) any warehousing and shipping; (i) the identity of any known subsequent purchaser; and (j) the intended shipment route, the shipment date, shipment destination, point of departure and consignee.

In order to understand how these requirements can be fulfilled and by whom, they must be analysed in the context of the operational activities carried out by the tobacco industry and its downstream supply chain for the production, warehousing and distribution of tobacco products, as well as the supervisory activities that must be performed by the controlling authority. These are illustrated in the tables below.

ADMINISTRATION AND UIM PROVISIONING		
Operational activity	Analysis	Conclusion
Licensing, registration and administration of economic operators	As per Article 6 of the Protocol, producers and importers (and possibly also traders and carriers) must undergo a licensing process. The tracking and tracing system should be used by the Authority to register and administer the licence, for instance in such a way that an economic operator whose licence has been suspended or revoked cannot use the system.	This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.
Ordering of UIMs	This operation allows the tobacco industry, in good standing, to request unique, secure and non-removable identification markings ('UIMs') that must be placed on packs and aggregate packaging levels. Because it needs to be performed according to production plans, interaction with the tobacco industry is strictly required.	This operation can be delegated to the <b>tobacco industry</b> .
Management of UIM orders	This operation requires the Authority to review orders, and to approve / reject orders, based for instance on the good standing of the operator with regard to their fiscal obligations.	This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.
Generation of UIMs	This operation consists of generating UIMs to be used for marking and for tracking and tracing the tobacco products, at pack as well as aggregate level (carton, master case, pallet).  In the language of Article 8 of the Protocol UIMs can take the form of 'codes or stamps'. As analysed in an article published by ITSA in December 2018 <sup>1</sup> , the usage of a tax stamp jointly carrying security features and unique identification should be considered as the only	This operation must be carried out by the <b>Authority</b> and cannot be delegated to the tobacco industry.

<sup>1</sup> How to Make Unique Identifiers for Tobacco Track and Trace Secure and Independent from the Tobacco Industry: A Standards-Based Approach, <https://www.tax-stamps.org/userfiles/files/How%20to%20Make%20Unique%20Identifiers%20for%20Tobacco%20Track%20and%20Trace%20Secure%20and%20Independent%20-%20a%20Standards-Based%20Approach.pdf>

	<p>option that safeguards the ‘secure’ attribute of the UIM.</p> <p>The set of generated UIMs represents a ‘baseline’ for subsequent reporting activities. There are no operational dependencies that justify any interaction with or delegation to the tobacco industry.</p>	
<b>Delivery of UIMs</b>	<p>This operation consists of delivering the requested UIMs to the economic operator. There are no operational dependencies that justify any interaction with or delegation to the tobacco industry, other than recording the hand-over of the UIMs to the tobacco industry.</p>	<p>This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.</p>
<b>Engineering and operation of the data repository</b>	<p>The data repository contains stakeholder and licensing data, user data (including Authority users), UIMs and track and trace data from multiple economic operators. This is possibly the most sensitive component of the system and must be protected by the Authority against potential attacks and misuse.</p>	<p>This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.</p>

#### MONITORING AND CONTROLLING

<b>Operational activity</b>	<b>Analysis</b>	<b>Conclusion</b>
<b>Field inspections</b>	<p>Field inspections are performed by competent authorities on an on-going (eg. at Customs posts), casual or risk basis. They are supported by tools that allow authentication of the security features of the UIMs, and to retrieve the associated traceability information.</p>	<p>This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.</p>
<b>Monitoring</b>	<p>In order to monitor compliance of the tobacco industry with regulations, the Authority analyses data collected by the track and trace system in the repository to detect suspicious patterns of activity and by performing risk-based inspections and audits.</p>	<p>This operation must be performed by the <b>Authority</b> and cannot be delegated to the tobacco industry.</p>

PRODUCTION		
Operational activity	Analysis	Conclusion
Application of UIMs	<p>As mentioned above, tax stamps jointly carrying security features and unique identification codes are the only option that safeguards the ‘secure’ attribute of the UIM.</p> <p>The process of applying tax stamps on tobacco packets must be done in accordance with the industrial packaging process, which in virtually all cases employs highly automated machines. Specialised tax stamp application modules are supplied by the packaging equipment manufacturer and are tightly integrated with the packaging machine itself through industrial automation techniques that include mechanical (eg. bracketry) and electric / electronic (eg. synchronisation signals) integration. Maintenance and operation of these machines must be done in a coordinated fashion and requires similar skills. For these reasons, it can be advantageous to delegate the tax stamp application activity to the same technicians that operate the tobacco packaging machine.</p> <p>It should be noted that not all UIM data elements required by Article 8 of the Protocol may be captured in the tax stamp’s unique identifier, as some of them (eg. date and time of manufacture) are only determined at the time of production. Some elements of the UIM therefore may need to be printed directly on the packs as ‘codes’, complementing the data elements of the UIM that are present on the tax stamp.</p> <p>Applying (eg. printing) these additional UIM data elements as codes on the pack should ideally also be performed by the Authority, as it is an integral part of the responsibility to generate UIMs. Possible derogations may be justifiable in certain cases, such as when</p>	<p>The application of tax stamps could be delegated to the <b>tobacco industry</b>.</p> <p>The printing of additional codes on packs should be performed by the <b>Authority</b> but may in certain cases be delegated to the tobacco industry (eg. in the case of imports).</p>

	products are manufactured abroad, in a country that is not a Party to the Protocol.	
Verification and reporting of UIMs	Once a UIM has been applied to a packet or an aggregate packaging unit, it must be verified using scanners on the production line, and it must be reported to the Authority by transferring the corresponding data (including product, machine, site, date, time, etc.) to the repository. This step is performed using scanners controlled by computers that are connected via a secure line to the data repository. This verification and reporting operation is quite sensitive, because any non-compliance (eg. failure to report) can open the door to fraud. Moreover, it is not particularly intrusive since it requires passive integration with the packaging line. For these reasons, it must be performed by the Authority without the risk of compromising line productivity of the tobacco industry or adding unreasonable cost.	This operation must be performed by the <b>Authority</b> and should not be delegated to the tobacco industry.
Capture and reporting of parent-child relationships between UIMs	In order to facilitate tracking and tracing of tobacco products from producers to importers and distributors, the parent-child relationship between UIMs applied / affixed to packets and all aggregate packaging units should be captured and reported to the data repository.  As far as the packet-to-carton relationship is concerned, cameras and other sensors must be placed often inside the machine that builds the carton ('carton maker'). Often, this is a highly complex machine with many moving parts, and significant mechanical and electronic integration is needed in order to capture all the required information. For practical reasons, it can be advantageous to have the packet-to-carton scanning equipment engineered, operated and maintained by the same technicians that operate the carton maker machine.	Considering the high degree of integration required with the existing packaging equipment, this operation could be delegated to the <b>tobacco industry</b> .

	<p>As far as the master case and pallet packaging units are concerned, various degrees of automation can be found in the tobacco industry, from completely manual to completely automated. In many cases, the tobacco industry has already adopted track and trace at these levels of packaging, for supply chain automation purposes, using commercial cameras, scanners, printers and software as needed.</p> <p>For reasons of practicality and cost-effectiveness, it can therefore be advantageous to have the parent-child relationship captured using the solution of choice of the tobacco industry, and to use these systems to report the required data to the Authority, using existing automated data-exchange protocols and interfaces.</p>	
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WAREHOUSING AND DISTRIBUTION		
Operational activity	Analysis	Conclusion
Capture and reporting of goods movements	<p>As per Article 8 of the Protocol, any warehousing and shipping, the intended shipment route, the shipment date, shipment destination, point of departure and consignee must be reported to the Authority. Nowadays this information is often already captured by the tobacco industry and the downstream supply chain using IT systems, such as Warehouse Management Systems, provided by several commercial vendors, and having it performed by the Authority instead (or in parallel) can represent an un-necessary burden not justified by system security reasons. For practical reasons, it can be advantageous to have it performed by the tobacco industry using the technology solution of their choice, and to use these systems to report the required data</p>	<p>In order to avoid duplication of efforts and for cost-effectiveness reasons, this operation could be delegated to the <b>tobacco industry.</b></p>

	to the Authority, via existing automated data-exchange protocols and interfaces.	
<b>Reporting of commercial information</b>	Per Article 8 of the Protocol, the name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer must be reported to the Authority. Nowadays this information is captured by the tobacco industry using IT systems, such as Enterprise Resource Planning, provided by several commercial vendors. The only practical solution is to have it performed by the tobacco industry using the solution of choice, and to use these systems to report the required data to the Authority, via existing automated data-exchange protocols and interfaces.	For practical reasons, this operation should be delegated to the <b>tobacco industry</b> .
<b>Capture and reporting of aggregation changes</b>	Changes to the parent-child relationship between UIMs at different levels of the packaging hierarchy must be captured and reported to the Authority. Because the carton is a retail sellable unit, such changes occur only from the carton upwards (carton to master case, and master case to pallet), and not below. The same analysis made above regarding existing equipment and software already in use also applies here. In order to avoid duplication of effort, it can therefore be advantageous to have it performed by supply chain stakeholders using the solution of their choice, and to use these systems to report the required data to the Authority, using existing automated data-exchange protocols and interfaces.	In order to avoid duplication of efforts, this operation could be delegated to the <b>tobacco industry</b> .

### 3. SUMMARY

The following table summarises the operational activities that could be delegated by the Authority to the tobacco industry and its downstream supply chain stakeholders.

<b>Process</b>	<b>Operational activity</b>	<b>Delegation</b>
<i>ADMINISTRATION AND UIM PROVISIONING</i>	Registration and administration of economic operators	No
	Ordering of UIMs	Yes
	Management of UIM orders	No
	Generation of UIMs	No
	Delivery of UIMs	No
	Engineering and operation of the data repository	No
<i>MONITORING AND CONTROLLING</i>	Field inspections	No
	Monitoring	No
<i>PRODUCTION</i>	Application of UIMs	Partial
	Verification and reporting of UIMs	No
	Capture and reporting of UIM parent-child relationships	Possible
<i>WAREHOUSING AND DISTRIBUTION</i>	Capture and reporting of goods movements	Possible
	Reporting of commercial information	Yes
	Capture and reporting of aggregation changes	Possible

In the selected cases mentioned above, delegation to the tobacco industry is justified by the high degree of technical integration needed at the engineering level, the need to avoid unnecessary duplication of efforts, and for cost-effectiveness reasons. Delegating any other activities to the tobacco industry can therefore be considered not to meet the 'strictly necessary' criteria of Protocol Article 8.13.

Insofar as illicit trade in tobacco products is an international phenomenon, it is important that all systems established by the Parties provide the required security by adhering to the above recommendations. Any national or regional system that fails to meet the required security requirements will create loopholes that will jeopardise the security of the global tracking and tracing regime envisaged by the Protocol. Examples of such systems are those established by the European Union (analysed in 4. below), and by the Economic Community of West African States (ECOWAS).

#### 4. COMPARISON WITH THE EU TOBACCO PRODUCTS DIRECTIVE

Based on the above analysis, the system established by the European Commission for the Tobacco Products Directive (TPD)<sup>2</sup> exceeds the level of delegation to the tobacco industry that meets ‘strict necessity’ criteria for the following activities:

- Engineering and operation of the data repository: a system of so-called ‘primary repositories’ are delegated to the tobacco industry, which must appoint ‘independent’ suppliers. As reported in various media, despite the apparent rigour of independence criteria set by the European Commission, the tobacco industry eventually appointed – and the European Commission approved – the suppliers who co-developed the Codentify system<sup>3</sup>. A so-called ‘secondary repository’ that contains a copy of data from all primary repositories is contracted by the European Commission from one of the primary repository suppliers. Again, the selected supplier is one of the main developers of the Codentify system. This shows that, however strict, independence criteria can be easy to meet and cannot justify the delegation of an Authority’s critical responsibilities to the tobacco industry.
- Generation of UIMs: the tobacco industry can generate unique identifiers at the aggregate level, which is not justified either for operational or cost reasons. Moreover, the procurement of security features is delegated to the tobacco industry.
- Application of UIMs: the tobacco industry is entrusted with the printing of codes onto packs, even for products produced in the territory of the Authority.
- Verification and reporting of UIMs: the EU has assigned this responsibility (via so-called ‘anti-tampering devices’) to the tobacco industry, which must appoint suppliers that meet independence criteria set by the European Commission. Again, despite the apparent rigour of these independence criteria, the suppliers of the Codentify system were eventually appointed to carry out these activities.

In order to effectively secure independence and integrity of the track and trace system, all suppliers, if any, should be selected and contracted by the Authority instead of the tobacco industry. The standard practice for doing so is through transparent, open and competitive public tenders leading to the appointment of providers bound to contracts drafted by the Authority.

Another area where the EU TPD falls short of meeting the Protocol requirements is in the definition of the UIM. While in Article 8 of the Protocol it is clearly stated in a single requirement that UIMs must be unique, secure and non-removable, in the TPD the regulation on unique identifiers (covered by Article 15) is separate from the one on security features (covered by Article 16). This allows unique identifiers to be non-secure, in violation of Article 8 of the Protocol. Moreover, security features that are separate from the unique identifiers are extremely weak, in terms of governance and technical requirements. Combined, these weaknesses have introduced fundamental vulnerabilities into the implementation of secure track and trace for

<sup>2</sup> 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

<sup>3</sup> <https://www.eureporter.co/health/2019/05/20/questions-abound-over-eus-track-and-trace-system/>

tobacco products, which go against best practices in the security industry as captured in various ISO standards (eg. ISO 22382 'Guidelines for the content, security, issuance and examination of excise tax stamps' and ISO 16678 'Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade'). A comprehensive analysis of the EU TPD limitations in this area can be found in an article published by ITSA in December 2018: 'How to Make Unique Identifiers for Tobacco Track and Trace Secure and Independent from the Tobacco Industry: A Standards-Based Approach'<sup>4</sup>.

## 5. CONTACT ITSA

Don't hesitate to contact us for further information or for answers to questions not covered above. We stand ready to contribute to and advise any stakeholders of the WHO FCTC Protocol on the implementation of a track and trace system, leveraging the expertise of our members in the security industry and drawing on their experience in assisting governments worldwide to fight illicit tobacco trade.

I look forward to hearing from you.

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May 2019

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<sup>4</sup> <https://www.tax-stamps.org/userfiles/files/How%20to%20Make%20Unique%20Identifiers%20for%20Tobacco%20Track%20and%20Trace%20Secure%20and%20Independent%20-%20a%20Standards-Based%20Approach.pdf>