PROPOSAL FOR AN FCTC PROTOCOL-COMPLIANT TOBACCO CONTROL SYSTEM BLUEPRINT

This document has been created by the International Tax Stamp Association (ITSA), a not-for-profit organisation composed of leading suppliers of tax stamps and track and trace systems to governments. Its aim is to contribute 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).

EXECUTIVE SUMMARY

Article 8 of the Protocol (entitled 'Tracking & Tracing')[1] sets forth the principles of a global tracking and tracing system that is independent from the tobacco industry. A common technical blueprint is needed to support parties to the Protocol in the implementation of systems complying with Article 8, which leverages best practices on the different approaches to combat illicit trade, and which are interoperable at the international level. A shared governance framework restricting tasks that may be delegated to the tobacco industry also appears necessary, in order to enforce independence and prevent weak national implementations, which could undermine the security of the global system.

The purpose of this document is to propose a technical and governance model that could be considered as a blueprint by parties willing to implement a Protocol-compliant system. The proposed model draws from best practices gained by tax administrations around the world in the fight against illicit trade in tobacco products. It strictly adheres to the independence requirements of Article 8 and resolves weaknesses that academics, civil society and industry experts have detected in the European Union Tobacco Products Directive (TPD) model, by ensuring that 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. The model is aligned with prior ITSA publications on governance[2] and security features[3] and with a guidebook recently published by the Framework Convention Alliance[4].

The proposed model is outlined below using language that aligns with Article 8, with some added recommendations on operational aspects and responsibility assignments.

a) In order to establish the required tracking and tracing (T&T) system, **each party shall set up and operate a national and/or regional database** and use it to register stakeholders

[1] Protocol to Eliminate Illicit Trade in Tobacco Products

[2] Tracking and Tracing of Tobacco Products: Defining Roles and Responsibilities in Compliance with the FCTC Protocol, ITSA, May 2019 (available from ITSA web site, www.tax-stamps.org).

[3] How to Make Unique Identifiers for Tobacco Track and Trace Secure and Independent from the Tobacco Industry: A Standards-Based Approach, ITSA, Dec. 2018 (available from ITSA web site, www.tax-stamps.org).

[4] Guidebook on Implementing Article 8: Tracking & Tracing, Framework Convention Alliance, Nov. 2019 (fctc.org).

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(manufacturers, distributors and wholesalers) and products, and to collect and report data on tax stamps and on all tobacco products manufactured or imported into their territory;

b) In order to implement the Article 8.3 requirement that unique identification markings be 'secure', **ITSA recommends parties to request that every retail saleable unit (pack and carton) manufactured or imported in their territory be affixed with a stamp issued by the competent authority of the destination market**, in line with the ISO 22382:2018 standard[5], which advocates stamps with multiple security features and unique identifiers[6];

c) **ITSA recommends the use of a secure and independent marking for tobacco products that are for sale in duty free areas or that are destined for an export market that is not a party to the Protocol**, **and which does not issue tax stamps**. This secure marking could take the form, for instance, of a generic 'export' or 'duty free' stamp and be applied under the responsibility of the competent authority where the product is manufactured. If such a product is found in a market other than the intended one, it will be readily recognised as illicit, and allow retrieval of traceability information that will help with investigation and prosecution;

d) As a key enabler of global interoperability, **ITSA recommends using the ISO/IEC 15459:2014/15 standard[7] to encode the unique ID of each stamp and of each entity registered in the T&T database** (e.g. manufacturer, site, product);

e) In order to protect the system from tampering attempts, **ITSA recommends parties to independently set up and operate automated production monitoring equipment on each manufacturing line located in their territory**, using scanners to verify the presence of the required stamp on each pack and each carton, to scan the stamp's unique ID and report it in near-real time to the national database, along with the timestamp and the identifier of the packaging machine. The proposed monitoring equipment shall also be capable of detecting and reporting tampering attempts, such as unauthorised switch-off, disconnection, or opening;

f) **ITSA recommends parties to delegate the obligations of Article 8.4.2 to tobacco manufacturers**, which requires printing the following information on each package (including pack, carton, master case, and pallet): date and location of manufacture, product description, manufacturing facility and where available the intended market of retail sale. Tobacco manufacturers shall be required to capture and report this information in near-real time to their national database, along with aggregation information, ie. the parent-child relationship between IDs from different packages[8]. On one hand, this minimises impact on the manufacturing process, and on the other hand the risk of fraud is mitigated by the independent and automated production monitoring equipment, per paragraph (e);

[5] ISO 22382:2018: Security and resilience – Authenticity, integrity and trust for products and documents – Guidelines for the content, security, issuance and examination of excise tax stamps.

[6] While Article 8.3 offers the options of codes or stamps, ITSA recommends combining them (stamps with codes).

[7] ISO/IEC 15459: Information technology – Automatic identification and data capture techniques – Unique identification.

[8] Manufacturers may choose to establish the pack-to-carton association by using the unique ID of the stamps affixed to packs and cartons, or by generating and printing their own unique ID through a 'helper' code (see Section 6), while printing the information required by Article 8.4.2.

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g) In order to implement the provisions of Article 8.4.1, **tobacco manufacturers shall be requested to report shipment and commercial information to their respective authority's national database in near-real time**. This information includes: machine and production shift or time of manufacture for logistic units; the name, invoice, order number and payment records of the first customer: any warehousing and shipping; the identity of any known subsequent purchaser; and the intended shipment route, the shipment date, shipment destination, point of departure and consignee[9]. Again, this delegation to the tobacco industry is motivated by operational constraints, while risk of fraud is mitigated by production monitoring equipment;

h) Even though it is not explicitly required by Article 8, **ITSA encourages parties to establish a control and enforcement programme,** with back-office agents analysing the data available from their national database (e.g. monitoring alerts and checking consistency of data reported by stakeholders), and with field agents verifying the legal status of products in circulation, through portable/handheld devices capable of authenticating the stamp's security features and of querying T&T data;

   In order to gain increased oversight on illicit practices, ITSA also encourages parties to provide compliance verification capabilities to the public. This can be done for instance through freely available smartphone apps capable of scanning 2D barcodes, and of querying the national database;

   In addition, ITSA encourages the FCTC Secretariat to promote emerging technologies that would facilitate interoperability of database-querying among parties, and that have the potential to interoperate with the T&T systems used to fight illicit trade in other sensitive or taxed goods, such as alcoholic beverages[10];

i) In order to implement the provisions of Article 8.8, and with a view to minimising cost, **ITSA recommends the FCTC Secretariat to establish a Global Information Sharing Focal Point (GISFP) with the following basic capabilities**: (1) registration of national databases, and (2) issuance of security certificates to each national database based on Public-Key Infrastructure (e.g. X.509[11]). This simple architecture allows national systems to securely exchange between themselves, with minimal involvement of the GISFP.

With the exception of points (f) and (g), **ITSA recommends that all responsibilities above be assigned to a competent government authority and not delegated to the tobacco industry or a supplier of its choice**. In case the competent authority wishes to rely on the services of a third-party supplier, any contracts with the supplier shall be established directly by the competent authority, as opposed to delegating the contracting obligation to the tobacco industry. **ITSA**

[9] Article 8.4.1 requires reporting up to the first customer who is not affiliated with the manufacturer, however parties may decide to extend traceability requirements further down the supply chain.

[10] ITSA supports the use of a standardised Visible Digital Seal and the implementation of the 'Trusted Entry Point' concept of ISO 22381:2018 'Security and resilience – Authenticity, integrity and trust for products and documents – Guidelines for establishing interoperability among object identification systems to deter counterfeiting and illicit trade', as a general-purpose mechanism for signing a unique code using a Public Key Infrastructure, allowing the emergence of universal apps, which can dynamically authenticate the code, without hardcoded database addresses.

[11] X.509: Information technology – Open Systems Interconnection – The Directory: Public key and attribute certificate frameworks. www.itu.int

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recommends competent authorities to recoup any costs of the T&T system and its control and enforcement by charging the tobacco industry a fixed amount per stamp.

The proposed model offers the following benefits: (1) full adherence to the FCTC Protocol Article 8 requirements; (2) high resistance to fraud; (3) good alignment with the existing processes of fiscal authorities around the world, which rely on stamp programmes to ascertain excise tax liability, and for monitoring duty-paid status of tobacco products in circulation.

1. OBJECTIVES AND APPROACH

The blueprint model described in this document aims to achieve the following objectives:

1) **Offer a high degree of protection against fraud**, including undeclared / mis-declared / under-declared production and import, fake exports, and round-tripping. The proposed approach draws from best practices gained by ITSA members in partnership with tax administrations around the world in the fight against illicit trade.

2) **Guarantee independence from the tobacco industry**, as prescribed by Article 8 of the Protocol and by Article 5.3 of the FCTC, by limiting to the extent strictly necessary any tasks that may be delegated to the tobacco industry.

3) **Provide a global and interoperable T&T regime,** through a standard mechanism for data exchange, supported by the GISFP, which is to be established by the FCTC Secretariat.

4) **Ensure compatibility with the technical and operational constraints of the tobacco industry**. The proposed approach minimises disruption of the T&T system on manufacturing lines, and leverages scanners and dedicated software that may be already in use by logistics actors.

5) **Foster a competitive market of system suppliers and technology innovation**. While ensuring interoperability, the proposed approach avoids overly prescriptive recommendations that may lead to monopolies or technology lock-in, and promotes transparent procurement process, according to the ISO 22382:2018 standard guidelines.

2. STAKEHOLDERS

The proposed model includes processes carried out by the following stakeholders in the framework of the global Track & Trace (T&T) system:

FCTC Secretariat: primarily responsible for establishing the GISFP and facilitating global data exchange.

Competent Authority: national agency responsible for implementing the T&T system within the jurisdiction of a party, supported by the required regulation.

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Tobacco Industry: manufacturers, importers, distributors and wholesalers responsible for complying with regulatory obligations on marking and traceability of all tobacco products manufactured, imported, exported and distributed in the party's territory.

General Public: any person who consumes or has access to a tobacco product, and who has an interest in determining whether it complies with regulations.

3. DATABASE SET-UP

In order to implement Article 8.2 of the Protocol, each party must set up and operate a national (or regional) database. Each database will be used by the competent authority to manage data generated by the T&T system, including users, tobacco products, tax stamps, and all related events. ITSA provides no specific recommendations with regard to the technology of the database, other than the need to ensure that all the key concepts of information security (ie. confidentiality, integrity and availability) are considered in the design and operation of the system, along with the performance and storage capacity required to cope with the expected volume of users and data, over at least a 5-year period.

In order to implement Article 8.9, each national (or regional) database must be capable of exchanging data with the databases of other parties. Per Article 8.8, it is the responsibility of the FCTC Secretariat to establish the GISFP to facilitate data exchange between the national databases.

Various architectural frameworks can be envisaged for enabling exchange of data between national systems, facilitated by the GISFP. With a view to minimising cost, ITSA recommends the framework illustrated below, whereby the exchange of T&T data occurs directly between the national databases through standardised interfaces, alleviating the operational and cost burden of the FCTC Secretariat, which shall be primarily focused on the provision of directory services.

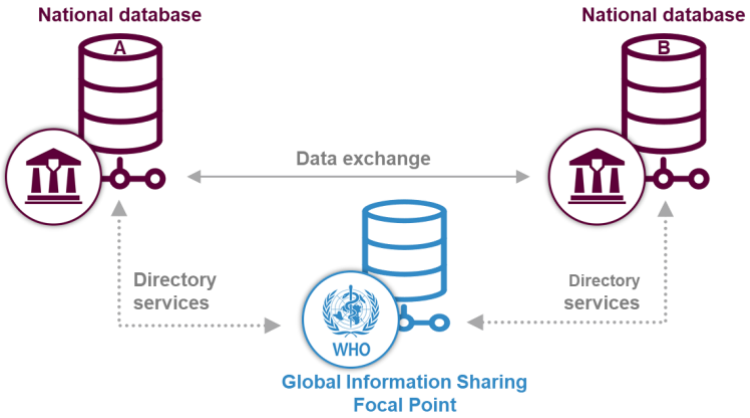

Figure 1: proposed connectivity framework between national databases and GISFP.

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In order to implement the GISFP directory service, ITSA recommends adopting proven open international standards. As an example, the Domain Name System (DNS[12]) that powers the internet provides name-address resolution with excellent security, simplicity and performance. Another example is the Lightweight Directory Access Protocol (LDAP[13]), a widely used industry standard application protocol for accessing and maintaining distributed directory information services.

In order to facilitate the secure exchange of data, ITSA also recommends adopting a standard-based public key infrastructure, whereby the FCTC Secretariat plays the role of a certification authority issuing digital certificates to national competent authorities. As an example, X.509 is a widely used standard for public key certificates, fully compatible with DNS and LDAP. Thanks to this architecture, the GISFP does not need to store any T&T data, and merely enables the secure communication between national databases, while retaining control with regard to who joins and remains in the system.

For exports of tobacco products from a country A to a country B, a 'push' mechanism is recommended, to be initiated by the national database of the territory (A) where the product is manufactured:

1) The national database of Party A authenticates itself with the GISFP and requests the address of the database of Party B;
2) The national database of Party A connects to Party B's database at the above-mentioned address, using its own private key to authenticate itself;
3) Any data exchanged between the two databases will then be encrypted using the respective keys, via standardised Application Programming Interfaces (APIs).

[12] IETF Network Working Group RFC 1034 and RFC 1035. IETF.org.
[13] IETF Network Working Group RFC 4511. IETF.org.

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4. STAKEHOLDER AND PRODUCT REGISTRATION

Each competent authority must provide and control access to authorised users of the system. Users can be internal (e.g. government agents) or external stakeholders (e.g. tobacco manufacturers, importers, distributors, wholesalers).

ITSA recommends competent authorities to register external stakeholders using all the information fields required by Article 6 of the Protocol, which includes information on the company, taxpayer ID, locations of manufacturing units and warehouses, tobacco products (e.g. product description, name), manufacturing equipment, and intended market(s) of sale of the tobacco products.

For each stakeholder, user profiles will include name, role, contact information, email address, and system access credentials (username/password).

5. UNIQUE, SECURE AND NON-REMOVABLE IDENTIFICATION MARKINGS

Article 8 of the Protocol provides several requirements on the marking of tobacco products:

- Per Article 8.3, unique, secure and non-removable identification markings (hereafter called unique identification markings), such as codes or stamps, are affixed to or form part of all unit packets and packages and any outside packaging;
- Per Article 8.4.1, the following information must be available, either directly or accessible by means of a link:

  (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;

- Per Article 8.4.2, the information in subparagraphs (a), (b), (g) and where available (f), shall form part of the unique identification markings.

A key requirement of Article 8.3 is that the unique identification markings be ‘secure’. Indeed, were markings not secure, illicit trade could easily be perpetrated by failing to apply them, by imitating or creating fake markings, duplicating them, or failing to properly report them to the

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competent authority for tax purposes. Drawing from decades of experience in the security industry, **ITSA recommends that the security attribute of the unique identification markings required by Article 8.3 be implemented via the mandatory use of stamps**, issued by the competent authority of the destination market, especially for retail saleable units, such as packs and cartons. ITSA recommends following the guidelines contained in the ISO 22382:2018 standard to ensure that the stamps have multiple levels of security features and that each stamp carries a unique identifier, printed in human- and machine-readable form, using standard carriers, such as GS1 2D barcodes;

ITSA also recommends unique, secure, and non-removable identification markings that are independent from the tobacco industry for products that are for sale in duty-free areas or that are destined for an export market that is not a party to the Protocol, **and which does not issue tax stamps**. This marking could take the form of a generic 'export' / 'duty-free' stamp and shall be applied under the responsibility of the competent authority where the product is manufactured. This ensures that all products in circulation or in transit within the country carry a secure marking, no matter the destination market, in order to protect against contraband practices, such as fake exports and roundtripping, thanks to the ability to retrieve information contained in the marking and electronically link to it in the national database.

In order to facilitate global interoperability, a global standard should be used to ensure uniqueness of identifiers carried by the stamps that are applied on the tobacco products, as well as those used to identify stakeholders (manufacturer, importers, distributors and wholesalers), sites, machines, and tobacco products (stock-keeping units). **ITSA recommends using the ISO/IEC 15459: 2014/15 standard** which requires competent authorities or their system suppliers to obtain a unique Company Identification Code (CIN) from an organisation that has been accredited as an Issuing Agency by Advancing Identification Matters (AIM), the international registration authority for the ISO/IEC 15459 standard[14]. This mechanism is illustrated in the figure below.

[14] ITSA is one of approximately 50 organisations that have been accredited by AIM as an Issuing Agency (IA code = WAA), and already provides CIN codes to its members. As an alternative method to complying with the ISO/IEC 15459 standard, competent authorities or their suppliers may seek to obtain an Issuing Agency Code directly from AIM. Another possibility would be for the FCTC Secretariat to obtain an Issuing Agency Code from AIM, and to issue CIN codes to competent authorities.

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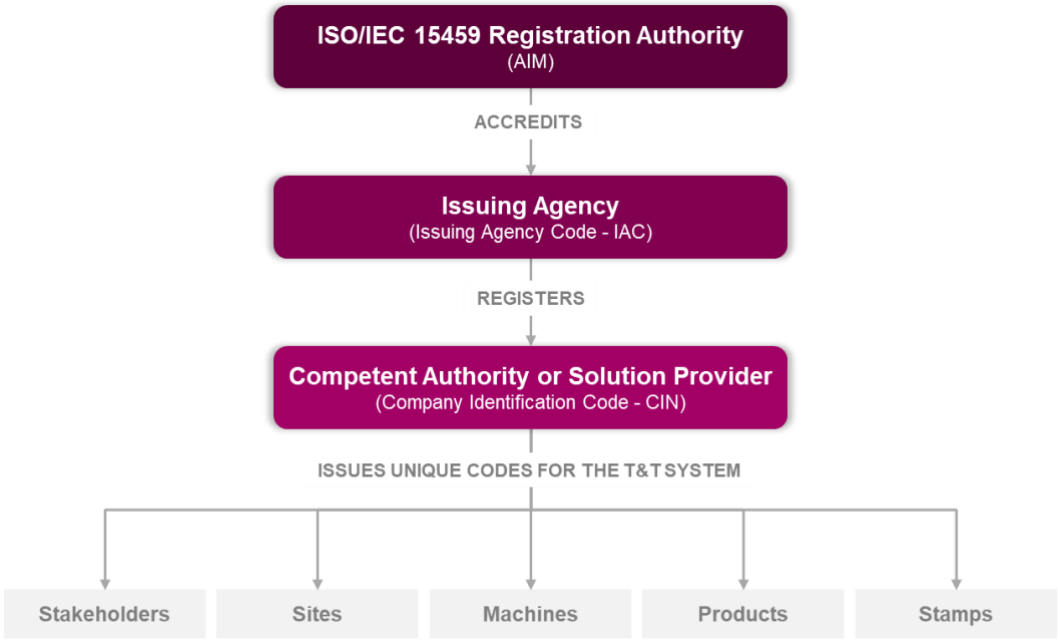

Figure 2: mechanism for issuing unique codes.

Once a competent authority (or a system provider on its behalf) is granted a CIN, globally unique identifiers can be generated for stakeholders, sites, machines, products and stamps by just generating codes that are unique within the scope of a given party and by using the CIN as a prefix (e.g. <CIN><StakeholderID>, <CIN><SiteID>, <CIN><MachineID>, <CIN><ProductID>, <CIN><StampID>). With regard to stamps, ITSA recommends using randomised generation algorithms for <StampID> to minimise the probability of their being guessed.

6. GENERATING AND APPLYING UNIQUE IDENTIFICATION MARKINGS

Article 8.4.2 requires the unique identification marking applied to the tobacco products to include information that is known only at the time of production (e.g. date of manufacture, manufacturing facility). Due to operational aspects of the manufacturing and distribution of tax stamps, encoding this information on the stamp itself would create significant challenges for the supply chain of stamps, and therefore for the manufacturing of tobacco products, resulting in significant delays and cost. For this reason, **ITSA recommends implementing Article 8.4.2 by printing or engraving the corresponding information elements directly on the package**, at the time of manufacture.

The combined provisions of Articles 8.3, 8.4.1 and 8.4.2 on the unique identification markings are therefore implemented with two components: the unique ID of the tax stamp (henceforth called '**UIM$_{GOV}$**'), and an additional marking that shall be printed or engraved on the packaging, and that captures the information elements required by Article 8.4.2 (henceforth called '**UIM$_{IND}$**'). The remaining fields required by Article 8.4.1 shall be accessible electronically via a link to the national T&T database, using the combined unique identification marking as a key (cf. figure below).

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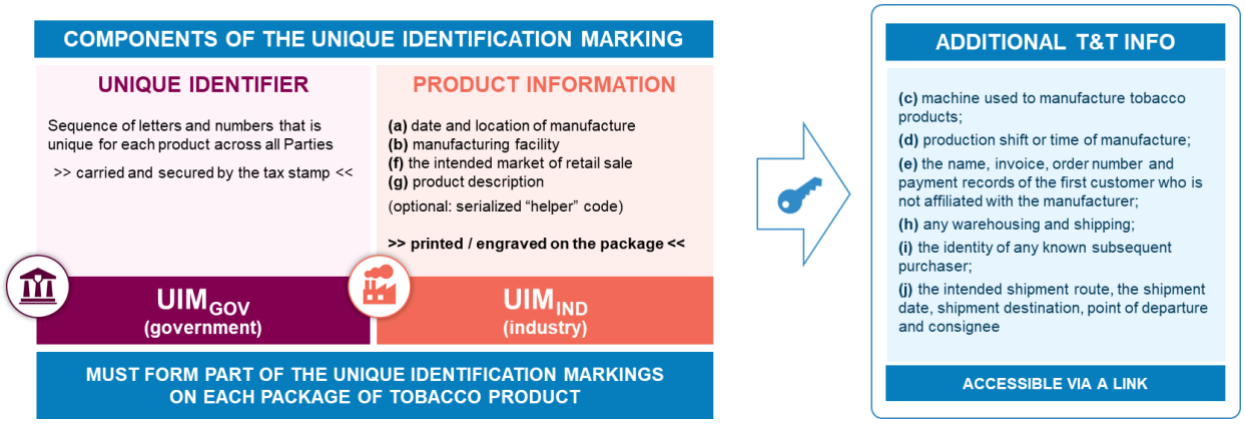

Figure 3: components of the unique identification marking.

These two UIM components have different characteristics. On the one hand, the UIM$_{GOV}$ is generic and product-neutral; provided it complies with the ISO/IEC 15459 standard syntax (ie. <CIN><StampID>), it can be generated by the competent authority (or a system supplier contracted by it) and electronically linked to a manufacturer prior to the manufacturing of the tobacco product. On the other hand, UIM$_{IND}$ is product-specific and contingent on information that is available only at the time of manufacturing; for this reason, ITSA recommends that the UIM$_{IND}$ component be generated and applied to the products by the tobacco industry.

Figure 4 illustrates the recommended solution for applying the UIM components to various packaging levels.

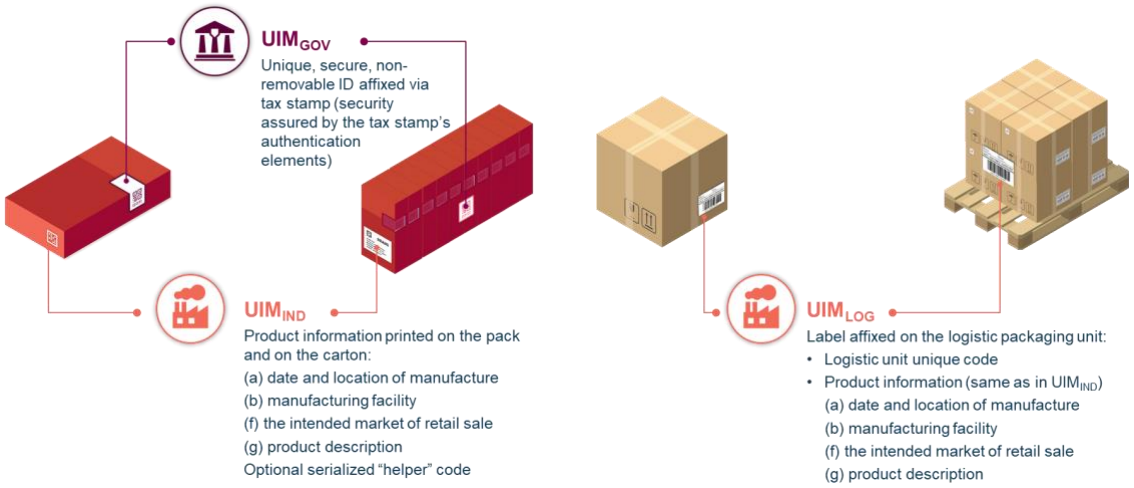

Figure 4: illustration of the unique identification marking applied to different packages.

For packs and cartons, the UIM$_{GOV}$ component is provided by the tax stamp, which is affixed to the product packaging during the manufacturing process, ensuring the marking is unique, secure and non-removable. Affixing the stamp to the pack and carton is performed under the responsibility of the manufacturer using commercially available automated label applicators that are widely used around the world. The UIM$_{IND}$ component is printed/engraved directly onto the

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pack and the carton[15], using commercially available equipment, also sourced and operated by the manufacturer. In order to facilitate aggregation (ie. capturing the parent-child relationship), the tobacco industry may want to add a serialised 'helper' code to the UIM_{IND} component, as an alternative to using the UIM_{GOV} code carried by the stamp.

Master cases and pallets are logistic units not meant for retail sale, and may be opened, closed, and replaced as needed by distribution chain operators without compromising the integrity of a consignment. In order to avoid excessive complexity for the supply chain, **ITSA recommends that a third type of marking, called 'UIM_{LOG}' be delegated to the tobacco industry (manufacturers and distributors), consisting of the same information elements included in the UIM_{IND}, plus a unique identifier that is compliant with the ISO/IEC 15459 standard**[16].

7. AUTOMATED PRODUCTION MONITORING

Given that some components of the unique identification marking (UIM_{IND} and UIM_{LOG}) are delegated to the tobacco industry, it is essential for the competent authority to control that every retail-saleable package has been duly affixed with the proper stamp according to the destination market (domestic, foreign, or export/duty-free) and reported to the national database.

ITSA recommends competent authorities to achieve these controls by independently installing automated production monitoring equipment on each packing line (for unit pack and ideally also for cartons), using sensors and scanners to determine whether they have been affixed with a valid stamp, and to read and report each stamp's unique code.

The production monitoring equipment should be capable of reading the 2D barcode of the UIM_{GOV} at high speed without slowing down the manufacturing process. It should be connected to the national database and report the codes scanned along with the timestamp in near-real time, with the ability to buffer data in case of connectivity issues, and to synchronise when connectivity is re-established.

Should it fail to detect a tax stamp on a pack or carton, the production monitoring equipment should generate an alert, both to the factory operator and to users from the competent authority.

Finally, anti-tampering capabilities should allow for the detecting and reporting of unauthorised attempts to open the production monitoring equipment or access the power switch.

ITSA recommends competent authorities to source the production monitoring equipment by contracting independent suppliers, as opposed to delegating the contracting obligation to the tobacco industry.

[15] Today many cartons are packaged using a clear polypropylene wrapping film. In this case, a commercial label is often applied for branding purposes, which can be leveraged for printing the UIM_{IND} code.

[16] Examples of ISO/IEC 15459-compliant unique codes are the GS1 Serialised Global Trade Item Number (SGTIN), which is widely used in the fast-moving consumer goods sector, especially for master cases containing products of the same stock-keeping unit (SKU), and the GS1 Serialised Shipping Container Code (SSCC), widely used for both master cases and pallets, and that must be used when mixing multiple SKUs together.

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The automated production monitoring equipment proposed here bears some resemblance with the concept of the anti-tampering device introduced by the EU TPD, although it has fundamental differences, outlined in the table below.

	Automated production monitoring equipment	EU TPD anti-tampering device
Verification capabilities	Detects the presence of a pack or carton on the manufacturing line Detects the stamp and scan its 2D barcode from each pack and carton	Video or log file
Connectivity	Connected online with the national database	Offline (can be accessed by auditors on premises)
Contracting entity	Competent authority	Tobacco industry
Anti-tampering capabilities	Generates automated alerts in case of missing stamp / unreadable barcode / unauthorised access to electrical or electronic components	Local memory that cannot be further altered by an economic operator

Table 1: differences between proposed automated production monitoring equipment and the EU TPD anti-tampering device.

8. REPORTING OF MANUFACTURING ACTIVITIES

Figure 5 below illustrates the various stages of the tobacco product manufacturing and packaging process. These indicate the various components of the unique identification markings that are reported by the production monitoring equipment under responsibility of the competent authority (coloured in blue) and those that are reported by delegation to the tobacco industry (coloured in brown).

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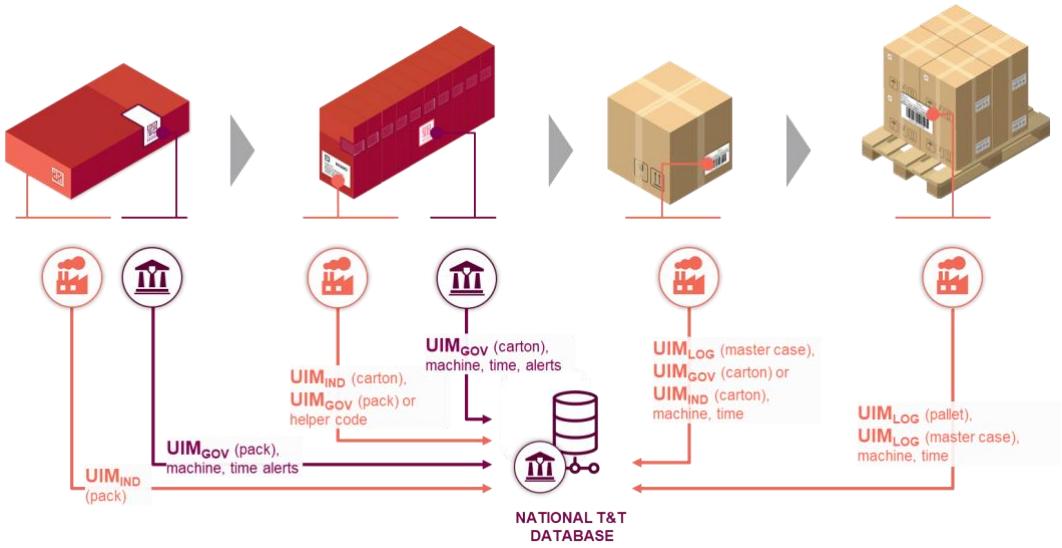

Figure 5: reporting of unique identification markings components during the manufacturing process.

In the packer machine, the tobacco manufacturer will use a printer to print the UIM$_{IND}$ component on the pack, a camera to verify its readability, and computing equipment to report the data to the national database. In case of a non-readable code, the manufacturer shall eject the pack from the line. In parallel, the production monitoring equipment independently reports in near-real time to the national database the UIM$_{GOV}$ codes scanned from the tax stamps, along with the identifier of the machine and the time of manufacture, generating alerts in case of non-compliance or tampering attempts.

In the carton maker machine, the reporting process is equivalent to the one described above for packs, with the additional obligation for the tobacco manufacturer to capture the **aggregation** information, through scanners that read the code from the packs that are included in each carton. This can be done by scanning the UIM$_{GOV}$ of packs and cartons, or via a serialised 'helper' code that the manufacturer may want to add to the UIM$_{IND}$ component.

For master cases, the UIM$_{LOG}$ marking is to be printed, verified and reported by the manufacturer. Aggregation must be captured with cameras or scanners capable of reading the marking of the cartons that feed into each case, either the UIM$_{GOV}$ code of each carton, or alternatively using the 'helper' code that manufacturers may want to add to the UIM$_{IND}$ code. Reporting must also include the identifier of the machine and the production shift or time of manufacture.

Pallets can be viewed either as a collection of master cases, or as logistic entities with their own unique identity. In the former case a pallet is identified by the set of UIM$_{LOG}$ of all master cases that compose it. In the latter, a dedicated pallet-level UIM$_{LOG}$ code must be generated by the manufacturer and reported to the national database, along with the parent-child links with all the master cases that compose it. Reporting must also include the identifier of the machine and the production shift or time of manufacture.

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9. REPORTING OF ADDITIONAL T&T INFORMATION

Article 8.4.1 provides a list of information elements that must be reported to the national database, and which are linked to the movement of tobacco products in the supply chain:

- Commercial information (the name, invoice, order number and payment records of the first customer);
- The identity of any known subsequent purchaser;
- Warehousing and shipping information, including the intended shipment route, the shipment date, shipment destination, point of departure and consignee.

This information needs to be linked electronically in the database to the marked goods by means of the unique identification marking (UIM_{LOG}) of the logistic packaging unit(s). Per Article 8.10, the economic operators that are concerned by this reporting obligation are the manufacturer and any operators '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'.

ITSA recommends parties to require this additional T&T information to be reported directly by economic operators, using equipment and software to be procured and operated under their responsibility. Again, the rationale for this delegation is to avoid adding unnecessary complexity and cost to logistic operations that may already employ scanning equipment and software to capture T&T data.

10. CONTROL AND ENFORCEMENT

Experience gained by ITSA members in collaboration with tax authorities from around the world indicates that the implementation of any T&T systems must be accompanied by controls and enforcement in order to effectively stamp out illicit trade. Even though it is not explicitly required by Article 8, **ITSA encourages parties to establish a control and enforcement programme.** Such a programme utilises back-office agents to regularly analyse data available from their national database (e.g. monitoring data automatically reported by production monitoring equipment, and checking consistency of data reported by stakeholders), as well as field agents who control the compliance of products in circulation, through portable/handheld devices capable of authenticating tax stamp security features and querying T&T data from the national database. The devices should collect legally binding evidence that can be used for enforcement actions, such as seizure and prosecution.

In order to gain increased oversight on illicit practices, ITSA also encourages parties to provide compliance verification capabilities to the general public. This can be done for instance through software apps capable of scanning 2D barcodes, and querying the national database.

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11. SUMMARY AND BENEFITS

This document describes a model for the implementation of the Protocol that, while adhering closely to the requirements of independence from the tobacco industry and those representing the interests of the tobacco industry, achieves all the objectives stated in Section 1, as summarised in Table 2:

Objective	Assessment of Proposed Model
High degree of protection against fraud	The proposed model includes tax stamps with multiple authentication elements to provide the needed security and protection against the highest fraud risks (e.g. undeclared/mis- or under-declared data, code duplication, fake exports)
High degree of independence from the tobacco industry	Delegation to the tobacco industry or any subcontracted party is kept to the strict minimum, ie. only for a subset of data elements that form the unique identification marking, which require the tightest integration with packaging machines, and for capturing and reporting of shipment and commercial data
Technically interoperable mechanisms enabling a global T&T regime	In the proposed architecture framework, a Global Information Sharing Focal Point (GISFP) established by the FCTC Secretariat provides directory services and digital certificates to the databases established by competent national authorities, securing direct data exchange between them
Ensuring compatibility with the technical and operational constraints of the tobacco industry	The proposed model is aligned with the operational constraints of the tobacco manufacturing and distribution process, ensuring minimal interference and avoiding the duplication of existing equipment and double data capture
Fostering a competitive market of system suppliers and technology innovation	The proposed model is supported by ITSA's members and the wider community of security system providers, guaranteeing fair competition among suppliers to the FCTC Secretariat and the competent national authorities. It fosters innovation with regard to security features, and can easily be kept aligned with evolving data exchange standards

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12. NEXT STEPS

In order to achieve the full benefits of the interoperable model contained in this document, the following technical specification documents should be drafted:

- Dictionary of master data elements and attributes to be used by all national databases for stakeholders, sites, machines, locations, products and stamps. An example of a possible dictionary is provided by GS1[17];
- Interfaces to be implemented by the GISFP, allowing competent authorities to register their national databases and to query the GISFP directory services. Existing international standards, such as X.509 and DNS or LDAP should be leveraged;
- Application programming interfaces (APIs) to be implemented by the national databases, allowing registration of master data (stakeholders, sites, machines, locations, products) by economic operators and/or by the competent authority, and reporting of event data by production monitoring equipment and economic operators. Existing international standards, such as EPCIS[18], could be used to define these APIs;
- Protocol and APIs to be implemented by the national databases in order to exchange data on tobacco products subject to import / export. The protocol should also cover the exchange of master data in order to ensure consistency between the databases of exporting and importing countries. Standards such as EPCIS could be used.

ITSA stands ready to provide further assistance to the FCTC Secretariat and the working group established by the Meeting of the Parties, and to provide subject matter experts that can contribute to drafting the above specifications.

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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[17] See https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf and https://www.gs1.org/standards/epcis/epcis-cbv/1-0

[18] https://www.gs1.org/sites/default/files/docs/epc/EPCIS-Standard-1.2-r-2016-09-29.pdf

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APPENDIX: COMPARISON WITH THE EU TPD

The following table provides a comparison of the main commonalities and differences between the proposed model and the one established by the European Commission for the implementation of the Tobacco Products Directive (TPD).

	Proposed ITSA model	EU TPD model
Governance	Most responsibilities are assigned to the party, or a system supplier contracted by the competent government authority	Most activities are delegated to the tobacco industry, or a supplier contracted by the tobacco industry[19]
Databases	One national T&T database per party (with the possibility of multi-party regions) One simple registry for the GISFP, under responsibility of the FCTC Secretariat	Multiple repositories indirectly controlled by the manufacturers One central repository controlled by the European Commission No databases under the control of national competent authorities
Interoperability	The proposed architectural framework provides for a global T&T regime, with minimal requirements for the GISFP, and direct secure data exchange between national databases	The architectural framework is limited to the EU The required model for the secondary repository is not globally scalable to meet the needs of the GISFP
Unique identifier generation	The unique identifier is made of: - A secure and unique ID is carried by a tax stamp, and is independently generated by the competent authority for packs and cartons - Date and location of manufacture, product description, manufacturing facility and intended market of retail sale, generated by the manufacturer	The unique identifier for packs is issued by an independent supplier (ID issuer) The ID for cartons, master cases and pallets is generated by either the ID issuer or the manufacturer None of the unique IDs are secure

[19] Despite the independence criteria established by the European Commission, the EU TPD model resulted in tobacco manufacturers contracting suppliers that have a long history of collaboration with the tobacco industry, and that have co-developed the Codentify system, which poses a risk of conflict of interest.

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	- For logistic packaging units a unique GS1 SSCC code is generated by the manufacturer	
Security features	Tax stamps issued by competent authorities are required for retail saleable units, with multi-level security features to protect against counterfeiting, imitation, duplication, and under-declaration	A generic set of five security features is prescribed for packs destined for the EU market, in line with a brand protection scheme (ie. not controlled by a competent authority), which opens the door to fraud
Production monitoring	A production monitoring device must be provided by the competent authority (or a contractor selected by the competent authority), which is capable of reporting in real time the lack of valid tax stamps on packs and cartons, and any tampering attempts	An anti-tampering device must be installed on each manufacturing line, however no remote/real-time access must be provided to the competent authority The device is procured directly by the tobacco industry, as opposed to the competent authority
Article 8.4.2	Printing and reporting of Article 8.4.2 data is delegated to the manufacturer	
Aggregation	Aggregation data is captured and reported by the manufacturer	
Shipment	The capture and reporting of Article 8.4.1 data other than that required by Article 8.4.2 is performed and reported by the manufacturer If required by the party, obligations can be extended to downstream supply chain stakeholders	The capture and reporting of Article 8.4.1 data other than that required by Article 8.4.2 is performed and reported by the manufacturer, and by all downstream supply chain stakeholders (up to the last distributor before retail)
Control and enforcement	Competent authorities must be provided with data analytics tools and with authentication devices for field inspections with online and offline capabilities Compliance verification tools should also be provided to the general public (e.g. smartphone apps)	The secondary repository must provide data accessible to competent authorities, and flat files that can be used for offline decoding of unique identifiers No provisions for inspecting the authenticity of security features No provisions for public verification

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