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TRACK & TRACE OF TOBACCO PRODUCTS – WHAT LESSONS CAN BE LEARNED FROM HOW THE EU SYSTEM WAS SET UP?

Henrik Czernomoriez, Uwe Holzmann-Kaiser, Lukas Strey

This study examines the differences in the implementation of the tracking and tracing system under the EU Tobacco Products Directive (TPD) compared to the FCTC Protocol, as well as the initial experiences garnered from their implementation in the EU.

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COP	Conference of the Parties
FCA	Framework Convention Alliance
FCTC	Framework Convention on Tobacco Control
GISFP	Global Information-Sharing Focal Point
ITP	Protocol to Eliminate Illicit Trade in Tobacco Products
ITSA	International Tax Stamp Association
NGO	Non-Government Organisation
MOP	Meeting of the Parties
OLAF	European Anti-Fraud Office
REST	Representational State Transfer
TPD	Tobacco Products Directive (2014/40/EU)
T&T	Track and Trace / Tracking and Tracing
UAE	United Arab Emirates
WBG	World Bank Group
WCO	World Customs Organization
WHO	World Health Organization

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1 Summary

The Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) was ratified under the Framework Convention on Tobacco Control (FCTC)[1] in order to specifically address measures to fight illicit tobacco trade. It entered into force in September 2018, after it was ratified by 40 parties[2]. For the European Union, a concrete application of the same principles as set out in the ITP can also be found in the Tobacco Products Directive (EU TPD)[3] which entered into force in 2014. Both systems foresaw the establishment of a tracking and tracing system for tobacco products within five years of their entry into force. This meant that the EU needed to ensure that it had a fully operational system ready by May 2019. The EU laid out the details of this system by one implementing regulation, one delegated regulation, and one implementation decision.

All parties to the ITP will have to install their own T&T system by 2023, and also a global information exchange mechanism will need to be developed and set up to facilitate the exchange of information between the different systems.

Since the EU was one of the first members of the ITP to introduce a tracking and tracing system implementing the requirements under the Protocol, and it is the only existing regional system sharing information between 28 different Member States since May 2019, the aim of this study was to see how the experience garnered from the process in the EU could be leveraged for the specifications for a global ITP implementation guideline.

The main conclusions are as follows:

In order to attain interoperability, it is important that:

- the **minimum level of information** is required for encoding in accordance with Article 8 ITP;
- the **structure (format)** is specified for the data to be encoded and stored using international or established industry standards, and;
- **interfaces** be rendered in a uniform manner. The latter can also be made available in more than one technology (web service, REST API).

Only data and processes **which affect**:

- interoperability with the global information point (data storage);
- the exactness in identification features to avoid ambiguity, or;
- the oversight and analysis functions among authorities

need to be centrally regulated, or at least be subject to guidelines to be incorporated by the parties when setting up their national or regional T&T systems. All other elements can be left to the autonomous decisions of the parties that are best placed to judge how to implement the system in their territory.

Fundamentally speaking, the EU model (approach, specification of implementation, and roll-out) has been designed to track and trace all tobacco products produced or circulating inside the European Union, but much of it can also be useful when setting up a national system. It specifies the comprehensive tracking and tracing of the whole supply

[1] (Abbreviation: ITP - Protocol to Eliminate Illicit Trade in Tobacco Products; Illicit Trade Protocol)
[2] Party: Country or group of countries (e.g. EU) that ratified the ITP
[3] (Abbreviation: TPD - Tobacco Products Directive)

chain, from manufacturing up to the last distributor before the first retailer. Depending on national priorities, the scope of such a system can easily be extended to also cover earlier stages such as tobacco cultivation or even include final points of sale as foreseen in the ITP. The EU model, however, already ensures that the full distribution chain of manufactured tobacco products is secured.

The EU model can clearly serve as a starting basis, even if some adjustments might need to be made by individual parties to avoid interoperability problems between systems. Indeed, the EU still has to find solutions on how to better connect with other regional and national systems to avoid issues such as double coding and to create a truly global system with easy information exchange between public authorities in order to aid the fight against the illegal tobacco trade.

The main challenge for the upcoming MOP[4] 2 and MOP 3 meetings in the framework of the ITP will be to address some of these issues to develop a strong information exchange platform and clarify fundamental guidelines and standards for implementation for the parties, taking inspiration from what the European Union has done well. Lessons of where the EU could have done better when it comes to deadlines and foreseeing enough time for testing will also be key.

[4] MOP – Meeting of the Parties (of the Protocol)

2 Introduction

Now that in the context of the *Framework Convention on Tobacco Control* (FCTC) the parties of the ITP are working on implementation guidelines on how to set up the worldwide *framework for tracking and tracing tobacco products* (ITP), it is an appropriate opportunity to look at how the European Union tackled a similar challenge when implementing the provisions on tracking and tracing as foreseen in the EU TPD. Whereas the rules for the EU system have been clearly laid out in its implementing and delegated acts, the work is still ongoing at the ITP level, so this study will focus on the provisions foreseen in the ITP itself when evaluating both approaches.

The regulatory provisions laid out in the ITP leave some room for interpretation in several articles. To this effect, the MOP of the ITP has set up two working groups between the parties to develop proposals for clearer rules and guidelines.

At the current time (July 2020), there are no official implementation guidelines or technical guidelines for the implementation of a T&T system under the ITP. The working group assigned to that task was supposed to present its findings and recommendations to the second MOP meeting which was planned for 16–18 November 2020 in The Hague. Due to the global pandemic, however, the second MOP meeting has been postponed by one full year until November 2021.

This ITP working group on tracking and tracing faces the challenge of spelling out guidelines that meet the Protocol's objective while also being practical for implementation among all signatory parties. The widest variety of technological frameworks and processes need to be observed in the countries of the individual contract parties.

Therefore, the working group has been tasked with developing the general principles for setting up the Global Information-Sharing Focal Point (GISFP), the central information exchange mechanism between the different parties, and to provide an overview of good practices on how to set up national or regional systems.

The recommendations of the working group will need to take into account the autonomy of the parties in designing their systems. Furthermore, the necessary guidelines have to ensure that the worldwide setup can accommodate the existence of a variety of systems already established or yet to be set up (e.g. the EU, Saudi Arabia etc.). For nations that have not yet ratified the ITP and become full parties, it is likely that the facility to integrate their existing system (e.g. Russia and the UAE) in the global framework will have a significant influence on their decision to join.

Ultimately, all global guidelines will need to be issued soon in order to ensure there is sufficient time for technical implementation before the 2023 deadline. With the postponement of the planned MOP 2 meeting, all associated deadlines should likewise be postponed. Since this will require a change to the FCTC Protocol, an alternative could be to extend the mandate of the working group to also cover developing guidelines and recommendations on the use of common standards and on how to address the problem of conflicts between national systems, resulting in double coding obligations, for example. If none of this happens, the time for implementation will become rather short. European experience shows that of all the elements that might influence the successful launch of a global or regional T&T system, planning enough time for testing and implementation is one of the most important.

2.1 Procedure

This study explores the tracking and tracing system set up by the EU from a theoretical point of view (the TPD itself), but also examines its concrete implementation to identify which lessons can be learned from what went well and what could have been improved. It also examines how the EU system interacts with other existing systems.

Moreover, this study examines how the EU system implements the provisions of the ITP and considers some of the arguments and criticisms of the EU system from different sources.

Since the ITP needs to integrate a wide range of different T&T systems, this study also covers pre-existing systems outside the EU to see how they are set up and to identify how this could impact the development of interfaces for a global ITP system.

The potential impact of the ITP implementation on the TPD system has been analysed focusing on the logic behind the EU system and how it might come into conflict with the global need for information exchange and common standards. This provides an interesting case study of issues that will need to be addressed in global guidelines to avoid conflicting obligations on the tobacco supply chain stemming from conflicting national legislations.

In all of this, the sole reference standard for estimations and analyses is whether the proposed regulations and measures are suitable for securing the legitimate supply chain, containing or stopping illicit trade, or at a minimum making it more difficult.

2.2 Background and genesis

Illicit trade involving cigarettes and other tobacco products is a global phenomenon. In 2017, the World Customs Organization (WCO) reported 7,378 confiscations of smuggled cigarettes, with a total of 2.379 billion cigarettes being seized [WCO, 2018]. In 2018, the number of confiscations rose to 17,606 involving a total of 1.968 billion cigarettes [WCO, 2019].

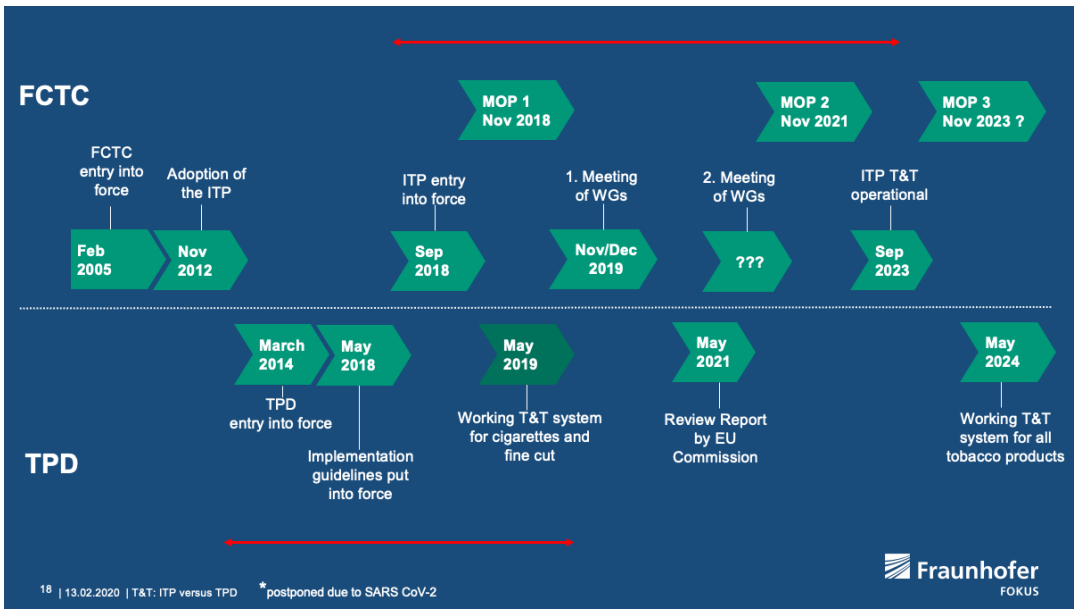
Based on the data from 2005 to 2011, OLAF estimates the annual tax loss in the EU due to the smuggling of tobacco products to be around €10 billion [European Commission, 2013]. Reports from Europol [Europol-1] illustrate how illicit trade is largely attributable to organised crime. According to the World Bank Group, some tobacco consumption is attributed to the availability of illegal cigarettes [WBG, 2019].

The Framework Convention on Tobacco Control of the World Health Organization (WHO) was constituted against the background of global tobacco consumption and the associated health risks [WHO, 2005]. According to Article 3 FCTC, the Convention aims to protect present and future generations from the health, social, environmental, and economic consequences of tobacco consumption. There are 182 parties of the Convention which entered into force in 2005 and has been signed by 168 countries (as at July 2020) [UNTC, 2003].

In the interest of continuing the fight against illicit trade, the fifth session of the Conference of the Parties (COP) adopted the “Protocol to Eliminate Illicit Trade in Tobacco Products”, which is designed to contain illegal trade involving tobacco products [WHO, 2013]. The Protocol’s declared objective is to hinder any and all forms of illicit trade involving tobacco products. One central component to attaining that objective is the introduction of a global tracking and tracing system consisting of national and regional systems. There are 61 parties of the FCTC Protocol (as at July 2020) and 54 countries have

signed the Protocol, one of which is the European Union [UNTC, 2012]. Figure 1 illustrates the timeline for the implementation of ITP and TPD regulations.

Figure 1 FCTC ITP / TPD Timeline



For the European Union, a concrete application of the same principles as set out in the ITP can also be found in the EU TPD which was adopted in May 2014 with the obligation to set up a tracking and tracing system for tobacco products within five years. This meant that the EU needed to ensure that it had a fully operational system ready by May 2019. The EU laid out the details of this system by one implementing regulation, one delegated regulation, and one implementation decision.

The established working groups (ITP) are currently (as at July 2020) still working on setting out the guidelines towards the parties on how to implement a T&T system and for setting up a worldwide information exchange mechanism.

Thus, the technical implementation of a European T&T system had to be defined by the EU within the scope of the TPD.

3 FCTC Protocol to Eliminate Illicit Trade in Tobacco Products (ITP)

The ITP is a coordinated international agreement for fighting illicit trade involving tobacco products. The first Meeting of the Parties under the Protocol was held in November 2018. The first MOP established working groups (WGs) to examine options for the technical implementation of the individual articles under the Protocol and come up with recommendations on a number of topics. One WG is specifically dedicated to Article 8 of the ITP: "*The working group will elaborate a comprehensive report compiling good practices and experiences on the implementation of tracking and tracing systems, as well as unique identification markings for cigarette packets and packages at national or regional level, and will prepare conceptual work in view of creating the global information-sharing focal point.*"[5] Results were supposed to be presented at the MOP 2 meeting, originally scheduled for November 2020; this has now been delayed to November 2021.

The Protocol has been ratified by a total of 61 parties thus far. Figure 2 shows the contracting parties [WHO, 2020].

Figure 2 Contracting parties of the ITP. Source: WHO, 2020

In order to contain illicit trade involving tobacco products, the Protocol defines measures intended to secure the legal supply chain. The primary component is a global tracking and tracing system which is intended to facilitate cross-border tracking and tracing (T&T). The global T&T system should cover national and regional systems, and the FCTC Secretariat has to set up a central point of access to information stored in the different national and regional systems, referred to as the *Global Information-Sharing Focal Point*. By September 2023, this GISFP should be fully operational, and all parties to the ITP will need to have a fully operational T&T system functioning in their territory. Further measures for securing the supply chain pertain to registration, licencing, logging of T&T data, and rules on sales over the Internet, duty-free sales, international transit,

[5] 05.06.2020: https://www.who.int/fctc/mediacentre/news/2019/expert-working-groups-cop-mop-advance-tobacco-control/en/

and free zones. In addition to securing the supply chain, the Protocol also addresses offences, international cooperation, and reporting. This study primarily addresses the provisions for securing the supply chain generally and the T&T system specifically.

ITP - Supply chain oversight

Securing and monitoring the supply chain is intended to prevent illicit trade involving tobacco products and production equipment from being diverted from the legitimate supply chain or the introduction of counterfeit products into the legitimate supply chain. Additionally, it is supposed to be possible to trace the origin of a product upon receipt. Monitoring of the supply chain is described in the following ITP articles:

- **Article 6 - Licence, equivalent approval, or control system:** Ban on the production, import, and export of tobacco products and its production equipment without a permit/licence.
- **Article 7 - Due diligence:** All natural and legal entities in the supply chain must subject their business relations to due diligence and comprehensive customer identification.
- **Article 8 - Tracking and tracing:** Introduction of a global tracking and tracing system for tobacco products, including a Global Information-Sharing Focal Point. All tobacco products (within five years after the ITP enters into force for cigarettes; within ten years for other products) must be marked with unique identifiers providing essential tracking and tracing information.
- **Article 9 - Record-keeping:** All natural and legal entities involved in the supply chain must maintain and provide records of all pertinent transactions.
- **Article 10 - Security and preventive measures:** General measures for containing the diversion of tobacco products into illicit trade, with sanctions issued as needed.
- **Article 11 - Sale by Internet, telecommunication, or any other evolving technology:** These sales are subject to the same conditions under the Protocol as all other forms of sales. Parties are encouraged to strictly regulate or consider banning retail sales via the Internet.
- **Article 12 - Free zones and international transit:** Monitoring of the production of and all transactions involving tobacco and tobacco products in free zones, forbidding the mixing of tobacco products with other products. Supervision during transit and loading of tobacco products and production equipment in free zones.
- **Article 13 - Duty-free sales:** All provisions and rules of the Protocol also apply to duty-free sales.

This is the general framework that mandates the ITP parties to set up a globally operational T&T system. The ITP parties will have to translate these general principles into concrete recommendations including global implementation guidelines and a set of agreed-upon standards in the same way that the EU had to for the provisions of the TPD.

There is one very important difference, however. Whereas the European Commission, together with the Member States, could impose standards and common rules in delegated and implementing acts, the FCTC Secretariat has no regulatory powers under the provisions of the ITP. Therefore, it will need to work via recommendations, guidelines, and commonly agreed principles and count on the goodwill or commitment of the parties/individual countries to follow such recommendations.

The only standards it can impose or control are those which the parties must respect to connect to the interface of the Global Information-Sharing Focal Point and the format in which parties will need to provide information via this platform.

The lessons learned from operating the EU system could prove useful while developing the ITP provisions. Moreover, since the T&T systems based on the ITP T&T framework will need to interact with all existing national and regional T&T systems, it is crucial to identify which potential issues need to be addressed to ensure that the TPD system and other existing systems can be seamlessly integrated into the new global T&T system.

This is why the recommendations and guidelines developed for a worldwide system must take inspiration and lessons from the EU's experience in setting up the only supra-national T&T system in operation. The experience garnered from EU implementation is described further in Chapter 4.3.

4 T&T implementations

Given the need to develop a system which can set international standards and guidelines and also works for existing T&T systems, it is helpful to analyse these systems in order to identify potential difficulties for integration and proven procedures. Although the current study mainly focuses on the way the EU system under TPD works and how it fulfils EU obligations under ITP, there are other T&T systems at work in different regions.

4.1 International T&T systems

In addition to the EU TPD, there are various national systems for the tracking and tracing of tobacco products. A number of these systems are cited below – without going into details – as examples in order to see what difficulties might arise in integrating them into a global ITP T&T framework.

The ease with which existing systems can be integrated into the ITP T&T framework without major investments or modifications might play a determining role in the decision of a country like Russia or the UAE to ratify the ITP and become a full member. Parties to the ITP will have to ensure that their system is compatible with the international framework, follow its specifications, and adopt its standards.

4.1.1 Russia

Russia has not yet ratified the ITP but has already set up its own multi-product T&T system that covers tobacco products as well as other consumer goods and the pharma sector. The 1.5-year timeline for implementation was relatively short but did allow for sufficient testing by economic operators before the system had to go live.

Under the Russian system, the manufacturers are responsible for generating the unique identifiers, but they have to include in it a unique code generated and provided by the state authorities.

Code activation takes place at the moment the system reports to the central database that the code has been sent to a printing machine in order to be applied to the packaging. The aggregation mechanisms for tobacco products are governed in a manner similar to the EU, where they are generated by the economic operators following imposed international standards and are reported to the central system.

Since the Russian system is not only developed for tobacco products, but a variety of products including pharmaceuticals, its scope goes beyond the obligations of the ITP and also goes further than EU systems. Products are tracked and reported up to the final point in the supply chain; the last scan takes place upon purchase by the end-user.

The system also foresees the use of a smartphone app for both authorities and consumers to verify the authenticity of the product.

Being highly reliant on Internet technology and apps, the system has experienced operational difficulties in regions with insufficient Internet connectivity. This is an important lesson for parties to the ITP, which might face similar difficulties when deciding on how best to implement their own systems.

4.1.2 United Arab Emirates and Saudi Arabia

The UAE and Saudi Arabia deploy T&T systems with comparable requirements. These systems focus on combating smuggling, especially in free trade zones, and also on supervising the payment of taxes. Therefore, the most significant feature is the secure and unique identifier. Saudi Arabia set a timeframe of six months for implementation after ratifying the law, which was very tight.

4.1.3 Burkina Faso, Ivory Coast, and Senegal

These three countries have existing national systems that were implemented on the basis of commercially available products. When setting up these systems, the obligations under the ITP were not yet clear, and as parties, all three will have to look at what modifications will be necessary to align their systems to meet all obligations and how best to connect them to the global T&T infrastructure and data exchange.

4.2 Europe

The EU's Tobacco Products Directive (TPD) must be implemented in the individual Member States. Although its adoption precedes the entry into force of the ITP, it has been conceived to meet all the EU obligations under the FCTC and ITP.

The main elements of the European tracking and tracing system have been specified in Commission Implementing Regulation (EU) 2018/574, which specifies the technical standards for a tracking and tracing system for tobacco products and governs the technical aspects for the implementation of a T&T system pursuant to the TPD. This is complemented by 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 (which sets out the main elements for the database structure, which supports the whole system) and Commission Implementing Decision (EU) 2018/576 on technical standards for security features applied to tobacco products. The T&T system has been operational for cigarettes and rolling tobacco since 20 May 2019 and will apply to all further tobacco products from 20 May 2024.

4.2.1 Roles within the TPD context

The TPD sets out a clear division of responsibilities and tasks between the authorities and the different economic actors.

Authorities

The EU system has been set up to guarantee that authorities establish very strict control across the entire system. This is achieved by reserving for themselves the generation of the unique identifiers, the exclusive access to the data in the system, and the exclusive right to decide which authentication elements are to be used in the security features.

Furthermore, it sets up a strict system of control over all the tasks to be performed by the economic operators by imposing the installation of an anti-tampering device on the

production line to verify the correct application of the code and the performance of independent audits on the correct functioning of the system. The system also sets and verifies the correct application of clear criteria to verify the independence of key service providers, such as ID issuers, data repository providers, providers of anti-tampering devices, and auditors.

National ID issuer

The national ID issuers play a crucial role in the overall system, since they generate not only the codes to be used in the unique identifiers to mark individual packs, but they also generate the unique codes by which all economic operators, facilities, and production machines in their territory are registered and can be identified in the overall system. Every Member State has appointed its own ID issuer according to their internal procedures. Economic operators request an identification code from the issuer of each Member State where they operate a facility and/or place imported products on the market. These codes are used in the T&T system in order to identify the places of origin and interim storage of tobacco products.

Data repositories

The data logged is stored by independent third parties. To that end, producers and importers must conclude contracts for the running of their *primary repository* with providers whose independence and technical capability are audited and confirmed by the European Commission. The European Commission also has to approve the final contracts as an extra guarantee of the independence of the provider. The data of every tobacco producer/importer is stored in such a primary repository. A copy of the data is transmitted to the secondary repository which acts as the central database and the heart of the entire system. All the data from the distribution chain is also transmitted to this database. This is also the place where Member State authorities can access all the tracking and tracing data. Given the crucial importance of its role within the system, the secondary storage provider is appointed by the European Commission itself. Manufacturers (producers) and importers do not have any access to the data in their primary repository or to the secondary repository.

Economic operators

With the term economic operators, the TPD refers to the producers/importers, logistics providers, and distributors in the supply chain down to the final economic operator before the point of sale (e.g. kiosk) where goods are sold to consumers. Every economic operator in the tobacco products supply chain must request a unique identification code from its national ID issuer. First points of sale are registered in the system and obtain unique identification codes. Additionally, all production and storage facilities used in the supply chain receive a unique facility code, and all production machines for tobacco products are registered with a unique machine identification code.

4.2.2 Technical implementation

Article 15 of the TPD (tracking and tracing) constitutes the foundation for T&T regulation. This article defines the unique identifier to be placed on or affixed to the unit packs of tobacco products. According to TPD requirements, the unique identifier needs to include all information on:

- date and place of manufacturing
- manufacturing facility
- machine used to manufacture the tobacco products
- production shift or time of manufacture
- product description
- intended market of retail sale
- intended shipment route
- identity of the importer into the EU, as applicable

The unique identifier is generated on the basis of this information by the national ID issuer and the producer/importer adds the date and time of production as a time stamp in the format YYMMDDhh to the code at the time of production.

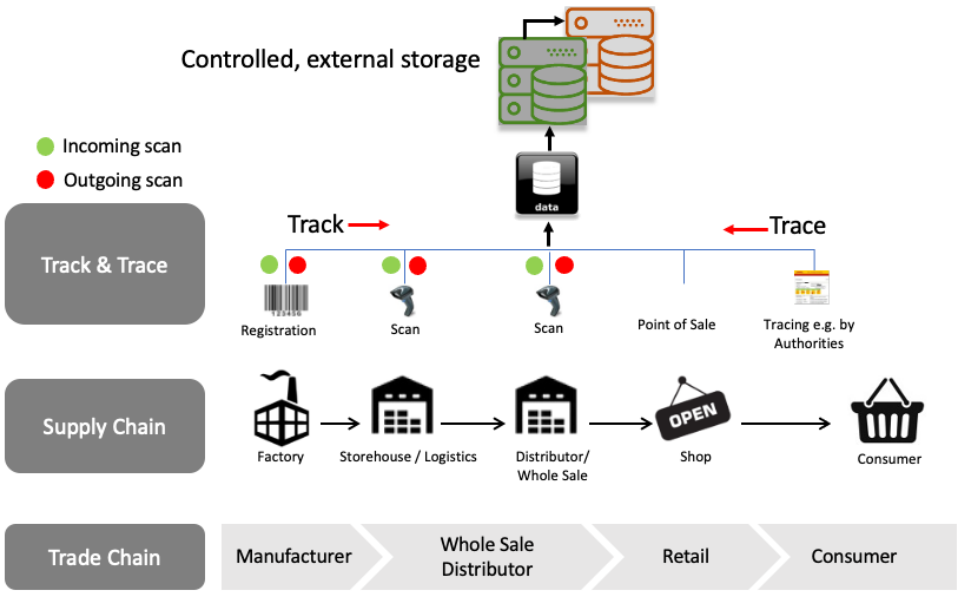
The code may not contain any data elements other than those indicated.

The following additional information is linked in the database system to the unique identifiers:

- the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure, and consignee;
- the identity of all purchasers from manufacturing to the first retail outlet, and;
- the invoice, order number, and payment records of all purchasers from manufacturing to the first retail outlet.

This information is provided by the economic operators to the central database to allow for full tracking and tracing of all movements.

Figure 3 Supply chain scanning under the TPD



At production, the unique identifier on the packaging level is checked for correct placement and readability directly after being affixed. A second layer of anti-manipulation equipment, known as an "anti-tampering device" installed and operated by an independent third party, verifies and logs all these operations to ensure that they are performed correctly.

All economic operators involved in tobacco products commerce are obliged to report the transition of packages into their possession, as well as interim storage, and the release of packages out of their possession. The process is illustrated in Figure 3.

External auditors, approved by the European Commission, perform regular checks to ensure that the data is correctly stored and all procedures are followed. The TPD requires all data to be stored within the EU. No economic operator has access to the stored data; this access is strictly reserved for public authorities. Marking and logging also applies to aggregations such as cartons, bundles of cartons (master cases), and all the way up to pallets.

The identifier on the pack level is encoded as DataMatrix code[6], QR code[7] or DotCode[8]. For identifiers on aggregated packaging, the data carrier types DataMatrix code, QR code, and Code 128[9] have been specified.

The regulation also defines the quality of the data carriers in line with ISO/IEC standards 15415:2011 and 15416:2016.

4.3 Experience

The European T&T system has been operational since May 2019. In the first year, the movement of around 22 billion articles among 700,000 registered economic operators was tracked by the system [Dentsu Tracking, 2019].

Since the launch of the system, it has already been necessary to perform several adjustments to the system, and further improvements and updates are expected. Given the complex and unique nature of the exercise of setting up a multi-country tracking and tracing system, this is rather normal. Below are some of the lessons that can be learned from the real-life experiences in the EU, so that similar problems can be avoided when setting up the worldwide T&T framework.

Timeline

Although a political agreement on the main implementing regulations for the TPD was achieved in December 2017, their formal entry into force only took place on 6 May 2018. With no legal possibility to delay the go-live date of the T&T system on 20 May 2019, this left just over a year for all authorities, service providers, and economic operators to appoint ID issuers, negotiate database contracts, and appoint primary and secondary repository providers, as well as build and adapt all the necessary IT systems, register all the economic operators, provide them with the necessary equipment, and set out the common ground rules. The provisioning of some of the specifications for use of the secondary data repository (the "data dictionary") were not published until February

[6] ISO/IEC 16022:2006
[7] ISO/IEC 18004:2015
[8] ISS DotCode Symbology Specification (AIM)
[9] ISO/IEC 15417:2007

2019 - three months before the system's launch – and serves as an example for the extremely tight time schedule determined by the above mentioned EU regulatory framework.

Member States were not able to start with the appointment of an ID issuer before the regulation entered into force and often had to follow internal rules on public procurement and in some cases adapt national legislation to implement the system. This has resulted in many Member States being extremely late in appointing ID issuers. In some Member States, it was not possible to conclude the whole process in time. With ID issuers only being confirmed one or two months before the system had to go live, this caused two serious problems:

- It became very difficult for them to successfully conclude the registration of all economic operators, facilities, and machines in their territory.
- It left very little time for them to develop their own specifications and code structure and for manufacturers and importers to onboard and test the systems of different ID issuers in their production environment.

Some feedback received from the data storage provider and ID issuer indicated that a lot of the initial problems in the system upon start-up were due to the lack of time to adequately test the integration of all systems. With a longer run-up period and an earlier definition of critical specifications, such as interfaces, as well as a more comprehensive test phase, it would have been possible to reduce additional expenditure and start-up difficulties. Therefore, it was necessary to make improvements with respect to address data, and multiple workflows had to be revised. When the EU system was rolled out, issues concerning the data quality of the reported product movements became apparent very quickly. This obliged the EU Commission, based on the experience of the secondary storage provider, to publish an information document for economic operators on the most frequently occurring standard reporting errors [European Commission, 2019c] and on how to address them.

One ID issuer that participated in this study stressed how important it had been that it had had enough time in the run-up to the go-live date to run a pilot operation involving economic operators in order to discover potential issues and address them before implementing changes. Although it had no obligation to do so under the TPD, this positive experience has convinced the ID issuer to continue to run a testing system with producers/importers of tobacco products before any release of new specifications. This is not a service offered by all ID issuers but can certainly be seen as a best practice to allow for better implementation of the TPD system.

The development of a mobile app that can be used by law enforcement and customs authorities to read out the identifier for on-site verification wasn't tasked by the EU. It was not part of the legal definition of the T&T System by the TPD. To fill the gap, the secondary data provider offered an already available inspection app for the EU system to provide all EU Member States with a common solution. However, different Member States had already started to work on their own applications in the past.

Lack of common standards leads to complexity

In addition to the fact that there was too little time to adequately test the system, live operation quickly revealed further issues with respect to specifications and even missing specifications. For example, there is no clear guideline for the Member States on the best structure of the unique identifiers, other than the elements summed up in article 15 TPD. This meant that the different ID issuers ended up using different code lengths

and even different standards. For example, when it comes to code structure, various national ID issuers use the standards from GS1; others use those from the Eurodata Council, and still others use their own standards. This yields complexities in reading out information, because the scanning system needs to know the type of code used in order to read out data correctly. This has resulted in repeatedly adjusted specifications for the scanning systems, because the systems need to be able to read and understand the codes issued by any EU ID issuer to meet the diversity seen in cross-border transactions.

Roll-out of updates to the system by the secondary repository (Dentsu) and the EU

In addition to the European Commission's implementing regulation, there are implementation specifications from the secondary repository provider regarding interfaces and data transmission. These specifications have already seen multiple necessary adjustments since the launch of the system, also to fix issues. Change requests have been made by all stakeholders.

Multiple parties involved (ID issuers and producers) have criticised numerous release plans that make it impossible to adequately test new releases before they have to be implemented. Even the European Commission had to acknowledge this after complaints by several Member States and agreed to delay the release date of some updates by as much as one month. In each case, too little time was originally allotted for preparing the changes, and the implementation phase was too short for developing and testing the respective processes.

Another criticism of some planned updates was that they didn't take into account the reality of the distribution and logistics processes. One update imposed the scanning out and in of products between two economic operators and facilities to be performed on the same aggregation level.

The decision to allow transloading during transport only on the same aggregation level was taken by the EU, even if technically, de-aggregation during transport, isn't a problem. De-aggregation on the premises was never in question. It reveals the impact of a decision on existing procedures and processes. The apprehensions of operators have been:

> This does not take into account that as products move along the distribution chain, the scanning practices vary, and very often the logistics providers work within their systems and processes on the level of master cases, rather than on the level of superordinate pallets. In the eyes of the logistics operators, this update has therefore only created additional work among the logistics providers and wholesalers without generating any benefit to the system with respect to more effectively securing the legitimate supply chain or fighting illicit trade.
>
> Logistics operators point out that ultimately, pallet damage caused during transportation can necessitate the scanning-in of undamaged individual elements – a situation not covered by the current specification.

EU evaluation report

TPD Article 28 obliges the European Commission to perform an evaluation of the TPD measures two years after the T&T system has become operational. This evaluation report must be submitted by 20 May 2021 to the European Parliament, the Council of the European Union, the European Economic and Social Committee, and the European Committee of the Regions. The report is intended to evaluate the functioning of the directive

and assess which possible updates, if any, to the Directive could be proposed, also taking into account recent developments in science and technology. Article 28 also explicitly states that one of the reasons to update the Directive could be to align its provisions to the development of new international rules and standards. This will also be an excellent opportunity to ensure the seamless integration of the EU T&T system into the global ITP T&T framework, if there is sufficient clarity on how it will be implemented. Although it is too early to assess what the exact impact the postponement of the MOP 2 meeting from November 2020 to November 2021 will have on the whole process, it does make it very unlikely that any FCTC implementation requirements and guidelines will be available in time in order to be taken into consideration.

However, building in these kinds of evaluation phases in the regulatory process can be very helpful to correct undesirable developments and take into account the emergence of new technological developments in regulations.

Differences between different national regulations applicable to export products and the need for international collaboration and global guidelines

While inside the European Union itself, the EU T&T system has developed clear rules to establish the competent ID issuers and ensure that national legislations do not contradict each other, the EU system has quickly encountered some issues when needing to coordinate with other existing foreign regulations and T&T systems. Some of these examples can be very helpful in identifying issues that global guidelines under the ITP T&T framework will also need to address as a priority.

The Australian plain packaging laws clearly define the exact layout and design of cigarette packaging. The obligation to mark all European exports (including to Australia) with a unique identifier, was in clear contradiction of Australian requirements. Although in this case, Australia has accepted changing their plain packaging regulations to accommodate the inclusion of T&T markings from other jurisdictions, it is clear that not every country will go to the same lengths.

Plain packaging laws are not unique to Australia but also apply in places like the United Kingdom, which is leaving the EU and accordingly is no longer subject to the TPD, and in other non-EU countries. Until there are clear international guidelines and agreements between the parties to the ITP, the EU will have to negotiate individual solutions with all these different countries to secure its exports.

This conflict stems from the current ITP requirements. A global, interoperable T&T system should be established on the one side but with all local or regional regulations still in place. This is a contradiction in itself:

Article 8.2 obliges all parties to "*establish, in accordance with this Article, a tracking and tracing system, controlled by the party* ***for all tobacco products that are manufactured in or imported into its territory*** *taking into account their own national or regional specific needs and available best practice.*"

This means that any product manufactured for export between two parties to the ITP will have to respond to two sets of requirements to mark the package with a unique identifier: those of the country of origin and those of the destination country. Without a clear system of precedence or international agreements, this could lead to the obligation to mark all packages with multiple codes. The impact of such a conflict can be clearly seen from the following conflict between the EU and Russian legislative provisions.

Since Russia has implemented its own T&T system for tobacco products, as described above, all EU exports to Russia need to carry two T&T codes; an EU code with export information and a Russian code with import information. This double marking requirement makes it impossible for both systems to use the same data carrier or the same place on the package. It would even require that both systems use different data carriers to avoid confusion and to ensure that Russian economic operators can identify which one contains the Russian code that can be scanned by Russian registers.

Solutions like virtual code pairing can potentially resolve some of these issues but are often very expensive and still require that the data carriers used by both systems can be scanned by all economic operators. This complexity has led to situations where producers decide to move production volumes outside the EU to places like Russia in order to avoid double marking requirements. It could also lead them to move production capacity to countries which are not party to the ITP and have no national T&T systems in place. This (undesired) side effect makes it necessary that the ITP T&T framework establishes clear guidelines to the parties on how to avoid double coding, since incompatible encoding strategies could otherwise have severe effects on individual local markets and production.

5 T&T comparison in FCTC ITP and EU TPD

The EU has created a T&T system that permits tracking and tracing in all EU states based on the same principles as those in Article 8 of the ITP. In doing so, it has set up a regional tracking and tracing system which fully encompasses all the obligations set out in the ITP. The EU TPD has even extended the scope of its provisions beyond what is strictly required under Article 8.

5.1 Objective

The ITP aims to translate general FCTC principles into more concrete measures to fight illicit trade. The TPD is how the European Union and its Member States meet their obligations under the FCTC and ITP. Logically, this means that both sets of regulations have identical objectives, namely the stopping of illicit trade, the monitoring and securing of the legal supply chain, and the ability to track and trace tobacco products throughout the entire supply chain. The way the EU system is set up takes into account the division of competences between the European Union institutions and the Member States, as intended by ITP Article 8 (2) mandating the parties to set up their own tracking and tracing systems, "[...] *taking into account their own national or regional specific needs and available best practice.*"

5.2 Processes and procedures

Both the ITP and TPD require the monitoring of the legal supply chain of tobacco products. However, their scope is different.

ITP Article 8 (10) only obliges the parties to: "*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.*" This means that as a minimum all production and import of tobacco products needs to be tracked and traced until it is sold by the importer or manufacturer to the first actor in the distribution and supply chain.

ITP Article 1 (12), however, clearly specifies that parties can decide themselves to extend the scope to retailers, transporters, wholesalers, and growers of tobacco.

TPD Article 15 (5) obliges Member States: "*to ensure that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession*." This means that in the EU all tobacco products are tracked and traced from production all the way down to the last economic actor before the first retail outlet where articles are sold to consumers. Therefore, all sales to retailers by distributors and wholesalers need to be registered, which is well beyond the minimum scope required by ITP Article 8 (10). At this point, the EU makes use of Article 1 (12) to extend the supply chain.

While this was decided by the EU for pragmatic reasons and to fully secure the legal supply chain, this may not be feasible in other countries due to circumstances relating to technology and organisation. It is important that the ITP foresees the necessary flexibility to account for the vastly different conditions under which customs and public authorities need to work in different parts of the world.

The other interesting aspect of the EU system is that it acts as a source of inspiration for the development of guidelines for the overall ITP T&T framework, since it is the only system which has already developed internal rules to determine the competent ID issuer for tobacco products exported from one jurisdiction to another. It has also had to develop common standards on data carriers and a data dictionary which all EU Member States had to adopt to allow all actors in the system the possibility to scan and report the products and to allow for a smooth data exchange between national enforcement authorities.

5.3 Involvement of economic operators

Tracking and tracing regulations can apply to all actors along the value creation chain such as tobacco producers and importers, distribution companies, and retailers. Accordingly, many different stakeholders are potentially affected by the implementation provisions of a T&T system. This is why concerned economic actors are very often consulted or implicated in the design and set-up of T&T systems, as is the case in many other industrial sectors[10].

Although the FCTC ITP is extremely reluctant to enter into any kind of dialogue or consultation with private economic actors, the experiences of the development of the EU T&T system can give guidance on how to best handle such contacts and the value they can have. The European Commission organised public consultations at several important moments in the decision-making process, requesting transparency in feedback from economic operators from the distribution sector, service providers, NGOs, public authorities, as well as tobacco manufacturers and producers. It also organised stakeholder workshops where remarks and clarifications could be given on the concrete proposals. According to many participants in these consultations and workshops, this has played an important part in helping the European Commission to move from a purely theoretical model to a very practical blueprint, which is much better adapted to reality: with the need to apply it to a high-speed production environment and a complicated and sophisticated (heterogeneous) logistics and distribution sector.

In order to move from a theoretical model to a concrete real-life system, it is crucial that the FCTC ITP also finds a way in which it can collect feedback and expertise from academics, technology providers, public authorities, and relevant economic operators. The FCTC Secretariat could guarantee full transparency and ensure that no particular economic interests are allowed undue influence on the decision-making process, in line with ITP Article 8 (13).

5.4 Technical aspects

All the information required by the ITP is already captured and stored under the TPD tracking and tracing system in the central database structure, consisting of the primary and secondary repositories. The EU system also stores information that is not required by the ITP, but which is not a problem with respect to the provision of basic data for the future global ITP information exchange point.

A very important element of the EU TPD system is that only the European Commission and competent public authorities have access to the data stored in the central system.

[10] For example, see the process for the establishment of an EU tracking and tracing system for pharmaceutical products as a result of the Falsified Medicines Directive.

Economic operators have no access to this data, and several safeguards have been put into place as a guarantee, including regular independent audits.

5.5 Criticism on the suitability of the EU TPD as a model for ITP

Some international non-governmental organisations like the Framework Convention Alliance (FCA) [FCA, 2019] and a number of economic interest groups (like the International Tax Stamp Assocation (ITSA) [ITSA, 2019]) have criticised the EU TPD system as not a good model for guiding other parties on how to implement an ITP-compliant T&T system. The criticism revolves around two elements. First, the system is criticised as being too complex and costly to be taken over by other parties. Second, certain elements of the EU system would not be compliant with the ITP provisions. The European Commission has firmly rejected this criticism in position statements [European Commission, 2019a & 2019b], and also the FCTC Secretariat has repeatedly confirmed to the European Union that they see no compliance issues at all with the EU TPD system. The European Courts have also rejected all legal challenges to the EU system as not compatible with the ITP[11].

However, it remains interesting to see the points around which the criticism of "non-compliance" with the ITP is centred:

- The TPD system sets out a clear division of tasks between public authorities and economic operators, which is being questioned by certain NGOs as problematic in light of ITP Article 8 (12) which states that: "*Obligations assigned to a party shall not be performed by or delegated to the tobacco industry.*"
  The EU Commission has replied that the TPD does not foresee any transfer of tasks affecting the EU's T&T regulatory content or enabling producers to perform regulatory functions under their own direction, which the ITP expressly reserves for the parties. Furthermore, it has set up a strict system of control over all the tasks to be performed by the economic operators by imposing the installation of an anti-tampering device on the production line to verify the correct application of the code and the performance of independent audits on the correct functioning of the system. The system also sets and verifies the correct application of clear criteria to ensure the independence of key service providers, such as ID issuers, data repository providers, providers of anti-tampering devices, and auditors, whose contracts need to be approved by the European Commission.

- The second main criticism is that the double repository system for data storage in the EU and the sheer volume of the data stored render the EU system too complex, making it unsuitable as a template for other systems.
  It is self-evident that the double repository system and the presence of multiple ID issuers is due to the fact that the EU TPD system is a regional and not a national system, uniting the individual T&T systems of 28 different Member States. For individual parties, it would make little sense to set up a structure involving both a *primary* and a *secondary repository provider*. However, the model (conceptualisation and procedure) can be adjusted to individual states and will then be significantly leaner.

[11] http://curia.europa.eu/juris/liste.jsf?num=T-396/18&language=EN
http://curia.europa.eu/juris/liste.jsf?num=C-553/19&language=en

- Another point of contention is how to exactly interpret ITP Article 8 (3) which states: "*each party shall require that 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 of cigarettes [...].*"
  Although the article clearly states that codes or stamps can be used to mark unit packs by affixing or integrating them onto the package, some providers argue that only printed codes – as an integral part of the package – can truly fulfil the requirement that the markings need to be "non-removable". Other interests argue that this article encourages the use of stamps, since they are easier to integrate and add a physical layer of security features in an environment under full control of the public authorities. The aim of this study is not to express any technological bias, since a careful reading of the article makes it clear that the ITP has explicitly allowed both systems. It is also interesting to read the reply of the European Commission [European Commission, 2019a & 2019b] on this topic, which clearly sets out their arguments on how the EU TPD system is fully compliant with Article 8 (3) and that its unique identifiers and the way they are applied gives all the necessary guarantees. The European Commission also points out that although it has decided under TPD to impose the use of security features to secure the packaging, this is clearly not an obligation under the ITP and that security features as such fall outside of the scope of the ITP.

The above discussion serves to emphasise that there is not one single T&T system which is compliant with the ITP requirements to the exclusion of all others. To the contrary, parties will have the choice from a variety of solutions and systems which will all be fully compliant with the ITP. This will, however, make it more challenging to design the overall ITP T&T framework in such a way that all parties can interact with each other and scan each other's products by making use of common standards for reporting to and interacting with the Global Information-Sharing Focal Point and by issuing clear guidelines on how to best address the risk of double coding.

6 Conclusions

The process for translating the articles of the ITP into concrete implementation guidelines has been steadily gaining momentum since the start-up of the work of the working groups in December 2019. Tasked with formulating recommendations to the MOP 2 meeting, which was originally planned for November 2020, this work has now been postponed to November 2021 due to the worldwide pandemic. Nonetheless, the ambition of the ITP remains unchanged: by September 2023 all parties to the ITP will need to either have a fully operational national T&T system in place or will need to have a joint regional T&T system, where applicable.

By that time, the Global Information-Sharing Focal Point for the exchange of information between the parties will also need to be fully operational. A clear set of standards and implementation guidelines will have to be adopted to allow for a truly global T&T infrastructure to support the fight against the illicit tobacco trade. This is an extremely challenging deadline as the European experience has shown.

Furthermore, in the time between the Protocol's ratification and today, the EU and other countries have passed resolutions on and/or already introduced their T&T systems based on the Protocol, which will need to be connected to the global T&T infrastructure.

So, what is the answer to the question of whether the EU TPD experiences can serve as a blueprint for the implementation of T&T systems?

As the EU model is a regional model designed to provide a solution for multiple Member States and is set up to function in a high-tech environment, it is unlikely that the EU model will be followed by other parties in its current guise. The global ITP T&T environment will need to accommodate a wide variety of pre-existing and future T&T systems. The existence of multiple and diverse T&T systems is not a problem in itself, provided they all pursue the same intended objective – stopping illicit trade to the greatest extent possible – and that the exchange and/or reading-out of tracking data is ensured for authorities via standardised interface technologies and information structures.

To avoid unnecessary complexity in connecting all these systems to the overall system as well as additional investments for parties who would need to adapt their existing systems, it is important that no time is wasted in reaching an agreement at the ITP level on commonly accepted standards and guidelines on how to connect T&T systems to the overall ITP T&T framework. At least it will allow existing systems enough time to prepare for changes and will also give a good indication on the technical specifications for parties to set up their systems by providing as a minimum a clear definition of the interfaces and structures that national systems will need to report to within the Global Information-Sharing Focal Point.

It will also significantly reduce costs for all economic operators and public authorities which, for example, will not have to invest in a variety of scanning equipment and software.

Failure to do so could lead to a very wide divergence of different and potentially incompatible T&T systems between parties, which could require additional investments to overcome this and to address other potential issues.

In this context, it is important to consider that countries which have not yet signed on to the ITP might be very reluctant to do so if the costs of introducing a new T&T system or adapting their existing one (a calculation encompassing resources, costs, and time) for meeting the requirements of an operative system cannot be justified from an economic and contextual perspective.

To that end, important lessons can be learned from the EU TPD implementation when it comes to setting up the global infrastructure and establishing new national T&T systems. This includes insights on how to appoint an ID issuer and select technology providers, how to use a limited number of international standards for possible data carriers, how to set up a database structure, and how to test and onboard the systems of ID issuers and databases into the manufacturing and distribution environment. It can also provide insight into how law enforcement and public authorities can make the best use of the available data collected in fighting illicit trade thereafter.

However, the most important lesson that can be learned from the EU experience is that the setting-up of a system does not happen in a vacuum and that a successful launch can only be realised if all impacted parties work together to identify issues and fix problems before the system goes live. This requires two crucial elements: a structured dialogue and enough time to test and correct where necessary.

6.1 ITP implementation, T&T

In order not to compromise the goal of setting up a truly global T&T framework under the ITP, it is very important that many of the issues described above are taken into consideration when setting standards and agreeing on common guidelines. It is equally important that this is always measured against the objective of setting up a system that will allow national and regional systems to exchange information with each other to help them fight the illicit tobacco trade and to secure the legal supply chain.

6.1.1 Realisation processes

The process and schedule for implementation must have a realistic time frame, provide the required specifications on time, and avoid too many changes in the specifications during system roll-out. In view of the short time frame for compulsory implementation by September 2023, the specification of the requirements needs to take place soon in order to have sufficient run-up time. If the EU time frames for the implementing regulation and specifications are used as a basis, then at least 1.5–2 years should be scheduled for planning, testing, and launch. This will become extremely challenging to achieve now, because any real decisions on the system have been postponed until November 2021 at the earliest, when the rescheduled MOP 2 meeting will take place.

In achieving a more realistic definition of processes and procedures, consultations with economic operators like technology providers (ID issuers, data repository providers, and international standardisation bodies), manufacturers, and distributors proved very helpful in the EU. As one building block on how to best set up the Global Information-Sharing Focal Point and on best practices regarding how to set up national T&T systems, it is up to the FCTC Secretariat to examine in which way this expertise could be utilised (via public consultation, a questionnaire, an expert study or some other way of sharing experiences). The FCTC Secretariat could ensure that this happens in full transparency and without giving any particular economic interests a disproportionate voice or undue influence in the decision-making process, in line with Article 8 (13). This could save some time in formulating concrete recommendations and identifying standards to be included in the specification of the ITP implementation requirements.

6.1.2 Regulatory need

The first question to address here is what can the scope of ambition of the global ITP framework be? Is the objective to try to create and impose a system on all ITP parties

that is as uniform as possible? Is it the ambition to set common rules to ensure that the existing and diverse systems can communicate and interact with each other and effectively exchange information? Given the fact that the ITP is not in the position to impose a system on all the parties and has to respect the sovereignty of states, the second option is the only realistic one available. Therefore, it is important to try to determine which elements will need to be taken into account when setting up this type of system.

Unique identifiers: data requirements and structure

The **minimum level of information** to be collected and encoded in the identifiers is specified in Article 8. It is harmless if more information is collected in individual systems, but the minimum required data needs to be uniform and interpretable everywhere.

The **structure (format)** for the encoded and stored data should be rendered in a uniform manner using international standards. While different structures/formats can be read by systems, this is not always without loss of information. The complexity of having to design IT systems to cope with a very large and divergent number of formats is enormous, so it would be advisable if at least guidelines could be provided on a limited set of possible data structures using internationally accepted standards. Since ITP does not have the authority to impose a single standard, and to avoid the risk of technology lock-in, it is recommended that a limited number of useful formats are included in the guidelines for implementation.

Interfaces

The interfaces to the data repository providers should be uniform. Permissible operations need to be defined. REST APIs or web service interfaces are the preferable means. Different interfaces are possible but do not offer any added value. Uniformity reduces the system's complexity among economic operators and avoids errors in bilateral/multilateral data exchange or access.

Global Information-Sharing Focal Point (GISFP)

It needs to be defined whether the information exchange point merely represents an access point (meta index) to local systems in various regions (Option A) or whether it is going to hold a copy of the data from local systems (Option B). In order to meet the ITP objective, at a minimum the interfaces (data, structure, access technology) to the global information point need to be defined.

(A) Should a global access point be required for access to the data sets in various systems, then external systems will have to offer uniform interfaces for access/analysis (see: Interfaces). This approach conserves resources but makes it necessary to merge data for cross-border validation.

(b) Should the objective of the ITP be the merging of various data sets among members for local collection, the imported data sets should only contain a minimum amount of data. The responsibility to supply an interface will change depending on the procedure (retrieval via GISFP or delivery of data). While this approach would make global analysis easier (with all data in one place), the sheer volume of data being collected poses a problem.

Data carriers

Various criteria are relevant to the selection of suitable data carriers:

- the capacity to present the requisite amount of data
- reliable placement in accordance with packaging and process steps
- availability as standardised global technology

Scanners available on the market are capable of reading different data carriers. Here, the EU TPD can be used as a possible inspiration for the selection made. In order to reduce complexity while avoiding technology lock-in, the EU selected three internationally recognised data carriers for unit packs and three for aggregation levels.

Unique identifiers

The structure and issuance of unique identifiers for economic operators[12], machines, and transporters etc. must follow globally defined rules. There can be room for manoeuvre for local implementation, but these identifiers need to be globally unique and retraceable for use in the whole system.

Validation

Merely collecting data without using it will not help to achieve the objectives of the ITP. Interfaces and apps for customs, law enforcement, and possibly for end-consumers need to be developed at the outset and be ready when the system goes live. The interfaces for end-consumers can be made open-source such that app developers can develop apps if the applications are not provided by an official source.

Moreover, it is necessary to study how to make this data available to end-consumers and private parties, taking into account the full spectrum of regulations on data privacy, such as the European GDPR.

Further requirements will lead to greater incompatibility among existing systems. Fewer requirements can result in additional expenditure for data exchange and collaboration. A sense of proportion is required with respect to the objective.

6.2 Summary

The EU was one of the first ITP members to introduce a T&T system implementing the requirements under the Protocol. The system has been deployed operationally in the EU Member States since May 2019.

Can the EU's approach be used as a blueprint? And what needs to be taken into account for a global solution?

The first question can be answered with a *yes*. This model can be applied for federations or regions, with the secondary repository being omitted for individual states. The EU's approach to the supply chain scope does not only comply with Article 8, but also allows for the extension according to Article 1 (12), which means that even tobacco cultivation

[12] Example: Production facilities outside the EU are registered by the importer which is importing the products into the EU. Should a production site work with multiple importers, perhaps from multiple Member States, then that production site would receive multiple identification codes. Consequently, this could lead to problems at the FCTC information exchange point if the same production facility can be identified by different means.

and/or other economic operators can be covered if parties wish to do so. It will work even as a global model; in this case, the T&T solution of the secondary data repository can be taken as a Global Information-Sharing Focal Point on the condition that it does not store copies of all locally logged data. Since the EU did not attempt to develop a model for everyone, it can still serve as a modifiable template.

In light of the experience garnered, information can be derived for the second question:

- It is necessary that the evaluation functions in data collection be included in planning from the outset, and that interfaces for authorities such as customs, police, tax investigations, and consumers be realised and rendered available, in full adherence to data privacy regulations.
- Globally necessary specifications for information infrastructures and interfaces need to be specified at an early stage and stably maintained.
- Wherever possible, international or established industrial standards should be used for defining data structures and data carriers.
- The operators of existing ITP T&T systems, IT service providers, and economic operators should be included in the implementation phase, in full transparency and with respect to the provisions of Article 8 (13) via stakeholder consultations and open dialogue opportunities.
- Complex projects require sufficient time for specification, coordination, and testing (6.1.1).
- Compatibility among existing systems should be taken into account.

Decisions with respect to the requirements within the scope of implementation provisions should always be made against the background of simplifying and securing tracking and tracing (including cross-border) as well as the monitoring of the origin and authenticity of a product.

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CONTACT

Henrik Czernomoriez
Business Unit Innovation Management
Phone +49 30 3463-7690
Fax +49 30 3463-99 7690
henrik.czernomoriez@fokus.fraunhofer.de

Fraunhofer FOKUS
Kaiserin-Augusta-Allee 31
10589 Berlin
Germany

www.fokus.fraunhofer.de

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