FCTC Protocol to Eliminate Illicit
Trade in Tobacco Products

Guidebook on Implementing Article 8: Tracking & Tracing

Commissioned by

Prepared by

FRAMEWORK CONVENTION
ALLIANCE

SOVEREIGN
BORDER SOLUTIONS

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1   FOREWORD

1.1   MESSAGE FROM FCA

It is difficult to claim expertise over a field that is as recent and vast as the Protocol to Eliminate Illicit Trade in Tobacco Products hereinafter "the Protocol". This guidebook does therefore not set out to provide all the answers to the questions policy makers may have while implementing the Protocol. However, the coming into force of the Protocol to Eliminate Illicit Trade in Tobacco Products in September 2018 has made the development of this guidebook not an option but a necessity.

In an effort to best serve its reader and explain a sophisticated mechanism in straightforward terms, this guidebook will be broken up in multiple chapters. This first part will provide a general overview and intends to be a starting point for a longer conversation that is just beginning and, hopefully, provide orientation for Parties to the Protocol implementation process that is now due to begin. It is equally directed at experts who may only wish to look up a certain item just as at people who are dealing with the issue for the first time and will want to read the guide in its entirety. More chapters, notably on tracking and tracing and the handling of tobacco products in free zones, will be added to this edition as the implementation process of the Protocol moves ahead.

Unless a Party to the Protocol has a clear understanding of how illicit tobacco manifests itself in the country's particular context[1] it is unlikely to have a significant impact on illicit trade. For instance, strategies that work to curb cigarettes that are smuggled across its borders are unlikely to work for cigarettes that are produced locally by unlicensed manufacturers; and strategies that work for counterfeit cigarettes are unlikely to be as effective in countering illicit whites. Policymakers are therefore strongly encouraged to view the measures set out in the Protocol as part of a holistic approach to combat illicit trade and not as a menu from which to pick and choose.

Readers should also consult two noteworthy publications in addition to this guidebook. Firstly, the "Report of the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products"[2], that analyses the technical option available to Parties to the Protocol and was mandated by the 7th Conference of the Parties (COP7) to the Framework Convention on Tobacco Control (FCTC). Secondly, a study from the World Bank Group titled "Confronting Illicit Tobacco Trade: A Global Review of Country Experiences"[3]. Both resources provide great insights into already existing systems to counteract illicit tobacco trades and offers valuable lessons learned.

Both publications are useful sources of information in this emerging field with only minor shortcomings and oversights. Their focus, however, differs from the approach this guidebook is taking. The added value of this guidebook is its practical, step-by-step approach aimed to help policy makers when they are tasked with putting the Protocol into practice, in particular its core provision of establishing a tracking and tracing regime (Article 8).

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[1] Financial Action Task Force (FATF). Guidance National Money Laundering and Terrorist Financing Risk Assessment -February 2013

[2] Available at: https://www.who.int/fctc/protocol/mop/FCTC_MOP1_Panel_Experts_Technical_Documents_supplementary_EN.pdf

[3] Available at: http://documents.worldbank.org/curated/en/677451548260528135/pdf/133959-REPL-PUBLIC-6-2-2019-19-59-24-WBGTobaccoIllicitTradeFINALvweb.pdf

Thus, this guidebook intends to be a resource for policy makers that need to implement the Protocol on country level. It provides an overview and historical context of how the Protocol came into being before providing an overview of the main elements of tracking & tracing (T&T) and offering guidance on how policymakers can choose an appropriate system for their particular context. This guidebook intends to contribute towards closing the knowledge gap between vendors of T&T systems and governments seeking to procure a T&T regime for tobacco products in order to fulfil their Protocol obligations.

Finally, the FCA does not pursue any commercial interests by publishing this guidebook but seeks to offer impartial expertise that contributes towards strengthening the Protocol as a whole, recognising that an effective global track and trace program could be an important tool to reduce illicit trade in tobacco products.

1.2   ABOUT THIS GUIDE

This guide is part I of a series written with the intent of educating Parties to the Protocol on the basic principles and concepts related to track and trace. It includes both technical as well as strategic guidance that is based largely on the success of other supply chain security programs, including those related to tobacco. There are many options and permutations that need to be considered and thus the guide does not proscribe any one solution model, technology or company but rather provides the basis from which Parties can make strategic decisions in relation to implementing their obligations under the Protocol. The technologies that comprise track and trace are in a constant state of evolution and over time new technological options may become available.

The technical sections of this guide provide a summary of the key building blocks related to track and trace with the intent of educating the reader on the terminology and core concepts that encompass track and trace. It also provides guidance related to emerging good practice based on existing implementations of effective solutions. Section four of this guide sets out a good practice checklist for Parties that intend to meet their obligations under the Protocol. The strategic recommendations are based on real-world experience of implementing large enterprise wide solutions in both the public and private sectors. They are based on generally accepted good practices and are intended to both minimise the risk of the overall project, but also to maximise the benefit by considering the Protocol implementation in the broader context of excise modernisation and transformation and building capacity to combat illicit trade. The overarching objective of this guide is to contribute to combating illicit trade in tobacco products which encompasses more than what track, and trace can offer.

1.3   ABOUT THE FCA

Framework Convention Alliance works to rid this world from the devastating health, social, economic and environmental consequences of tobacco and tobacco use. With hundreds of non-government member organisations from over 100 countries, the Alliance grew out of civil society's participation in the work that produced the World Health Organization Framework Convention on Tobacco Control in 2005, the first modern-day public health treaty. We are a leading advocate for including the FCTC and tobacco control in the international health and development

framework, including the Sustainable Development Goals. The Alliance is an influential voice for civil society at the FCTC Conference of the Parties.

1.4 ABOUT THE AUTHORS

Sovereign Border Solutions

Sovereign Border Solutions LLC. (SBS) is a boutique consultancy that brings together real-world experience, progressive thinking and proprietary tools and methodologies to deliver tangible results for our clients. SBS serves as objective advisors to clients in both the public and private sectors, including governments, companies, NGO's and international development organisations. SBS has extensive domain knowledge in customs, excise and secure supply chains. The company has established a unique offering in the track and trace domain and in assisting governments and NGO's with comprehensive modernisation of excise and in particular compliance with the Protocol. The company has assisted several governments and NGO's in developing technical specifications for the implementation of the Protocol. SBS was the principal author of the Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features.[4] SBS's team of professionals are all former customs, revenue and border executives bringing first-hand experience to the initiatives they support. SBS has never and will never work for the tobacco industry or its proxies.

Dr. Hana Ross

Dr. Hana Ross is the Principal Research Officer of the Economics of Tobacco Control Project at the University of Cape Town. She has over eighteen years' experience in conducting research on the economics of tobacco control and in management of research projects in low- and middle-income countries, including projects funded by the World Bank, the World Health Organisation, the Rockefeller Foundation, the Open Society Institute, the Robert Wood Johnson Foundation, the European Commission, the Bloomberg Global Initiative, and the Bill & Melinda Gates Foundation. Dr. Ross published more than 60 articles and independent reports on issues related to tobacco taxation, cigarette prices, costs of smoking, illicit trade, youth access laws and other economic aspects of tobacco control. She also co-authored the 3rd and 4th editions of Tobacco Atlas. Dr. Ross earned her B.A. and M.A. at the Prague School of Economics. In 2000, she received her Ph.D. in Economics from the University of Illinois, Chicago.

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[4] https://ec.europa.eu/health/sites/health/files/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

2   EXECUTIVE SUMMARY

2.1   *BACKGROUND ON THE PROTOCOL TO ELIMINATE ILLICIT TRADE IN TOBACCO PRODUCTS*

The Protocol to Eliminate Illicit Trade in Tobacco Products was opened for signature in January 2013. In June of 2018 the Protocol was finally ratified by the 40th Party and entered into force in September 2018. The work of implementation has now begun, and Parties have several deadlines to enact and implement its provisions which include the establishment of a system for secure track and trace for tobacco products as contained in Art.8 of the Protocol. Simply put, track and trace involves the ability to securely identify a unique item, track its movement through the supply chain and the ability to determine its status (intended market, tax paid etc.) and point of origin.

Art.8 of the Protocol sets out broad requirements for Parties to implement a tracking and tracing system. The text of the Protocol does not specify business requirements or technological options that are immediately actionable or implementable. Therefore, interpretation of these requirements and translation into operational and technical specifications is required. This guidebook offers insights, practical considerations and emerging good practice on how the supply chain control provisions can be practically applied. There is no one size fits all solution and each implementation will likely be unique in several ways. The guidebook does not prescribe a single system but rather sets out options and considerations given the current state of track and trace technologies in general and real-world case studies for tobacco products. However, there are certain concepts embodied in the Protocol that are not subject to wide interpretation. This guide attempts to highlight these concepts and introduce good practices and practical implementation considerations. Although tracking and tracing has been around for a long time in other industries, the practice is relatively new for tobacco products. The history of non-compliance of the tobacco industry and the economic incentives inherent in illicit trade are some key reasons for this. As such the Protocol requires that interference from tobacco industry in the selection, implementation and roll-out of a tracking and tracing regime must be avoided at all cost as set out in Article 5.3 of the WHO FCTC.

2.1.1   *Primary Objectives of the Protocol*

Illicit tobacco makes cigarettes cheaper, or more accessible, resulting in more people smoking, which in turn has negative health consequences and associated higher healthcare costs. The illicit trade in tobacco also has implications for tax policy: not only does it deprive governments of tax revenues; it also undermines the public health role of tobacco taxation aimed at curbing smoking.

The Protocol establishes an explicit objective: the elimination of all forms of illicit trade in tobacco products with a specific emphasis on supply chain controls. Figure 3 provides a summary of the key provisions as set out in the Protocol. In addition to the tracking and tracing requirements set out in Art.8, the Protocol also addresses other key policy measures and supply chain good practices including licensing, due diligence, record keeping, and security and preventive measures, as well as measures in relation to internet- and telecommunication-based sales, duty free sales, and free zones and international transit (see Section 5).

The 'Protocol' Key Requirements

Licensing	▪ Introduction of a licensing, equivalent approval or control system by a competent authority for any natural or legal person involved in the manufacture import and export of tobacco products and manufacturing equipment
Due Diligence	▪ Conduction of due diligence on all agents involved in tobacco industry', to ensure that sales are commensurate with legitimate demand and to report to the competent authority any evidence of activities in contravention of the Protocol
Tracking and Tracing	▪ Set of unique identification markings which will assist in determining the origin and the potential point of diversion and will enable the monitoring and control of the movement of tobacco products and their legal status
Record Keeping	▪ Control that all natural and legal persons engaged in the supply chain of tobacco, tobacco products and manufacturing equipment maintain complete and accurate records of all relevant transactions
Security and Preventive Measures	▪ Identification of any necessary measures to prevent the diversion of tobacco products into illicit trade channels to be taken by all natural and legal persons subject to licensing
New Channels	▪ Further provisions concern sales by Internet, telecommunication or any other evolving technology duty free sales of tobacco products…x
Other Controls	▪ The obligation to implement effective controls on tobacco and tobacco products in the Free Zones, including not mixing tobacco products with non-tobacco products at the time of removal from a Free Zone
International Cooperation	▪ Including information sharing and coordination — between law enforcement, prosecutors, scientists, administrators, and other officials and agencies

... from the WHO Framework Convention Tobacco Control (FCTC) and the Protocol to Eliminate Illicit Trade in Tobacco Products
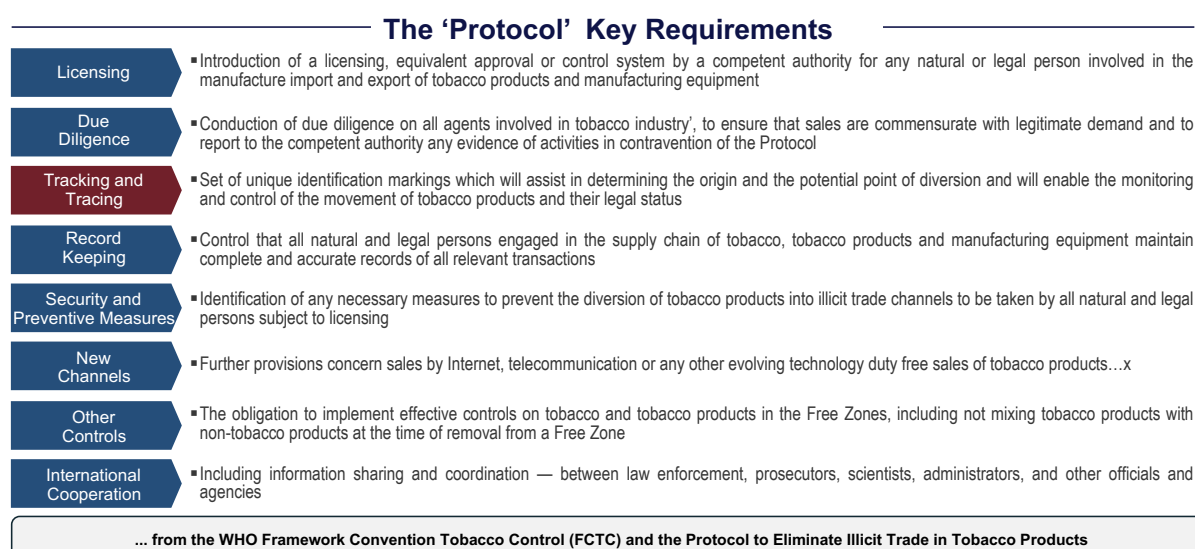
Figure 1 -Key Provisions of the Protocol

Going back to the Protocol's original inception, the track and trace system is based on mistrust of the tobacco industry when it comes to controlling their own supply chains. It cannot be compared to other supply chain security and compliance programs where incentives for voluntary self-compliance by industry is aligned to the objectives of regulators. Any notion of "industry standard" or industry implemented solution when it comes to tobacco track and trace is directly opposed to the objectives of the Protocol and inconsistent with the tobacco industry's history of serial non-compliance and outright criminality in jurisdictions that span the globe. It is for these reasons that Art. 8.12 of the Protocol clearly states that **"obligations assigned to the Party shall not be performed by or delegated to tobacco industry".**

2.1.2   Illicit Trade in Context

Research suggests that as much as 98 percent of illicit tobacco comes from licensed, legal tobacco manufacturers[5]; older research shows how as much as one third of export consignments go missing somewhere along the supply chain[6]; there are countless examples where known tobacco manufacturers were complicit in the smuggling of their own products the world over; and big tobacco manufacturers are repeat offenders when it comes to the over-supply of their products to markets knowing that the surplus will be diverted into illicit markets[7.] Tobacco is highly susceptible to smuggling and tax fraud, which not only costs governments money in terms of lost tax revenues, but also makes cigarettes cheaper and more accessible, thus diminishing the efficacy of tax-based cessation policies. This is due in large part to the considerable profits that can be made by illicit traders. Depending on the tax rate, profits on an untaxed container can be as high as 2,400 percent (more than the profits on cocaine or heroin) and the risk of detection is relatively low. Even the most advanced customs authorities have limited inspection resources given the volume of trade and typically customs is only able to physically inspect three to five percent of all containers.

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[5] https://tobaccoatlas.org/topic/illicit-trade/

[6] http://applications.emro.who.int/docs/Fact_Sheet_TFI_2014_EN_15313.pdf?ua=1&ua=1; https://www.icij.org/investigations/big-tobacco-smuggling/uk-considering-formal-investigation-cigarette-smuggling/

[7] http://www.theguardian.com/business/2014/nov/16/bat-fined-for-oversupplying-tobacco-in-low-tax-european-jurisdictions; http://theconversation.com/tobacco-industry-rallies-against-illicit-trade-but-have-we-forgotten-its-complicity-38760; https://euobserver.com/opinion/131592

Tobacco-related tax fraud is surprisingly simple to perpetrate. In the very simplest terms, tax is payable on all packs that are meant to be consumed within a country. Tax frauds therefore operate – at the most basic level – by either pretending to make or import fewer packs than was actually the case, or by creating the impression that the packs are destined for another country and that taxes are therefore not payable locally. To combat the illicit trade in cigarettes, an agency therefore needs to know with some certainty how many cigarettes were actually manufactured or imported, which market those packs are intended for; to subsequently be sure that the packs actually end up being sold on the markets they were intended for, and that taxes were paid in that market.

The single most effective strategy to curb illicit trade lies in better securing the tobacco supply chain – which requires the ability to track and trace cigarettes back to their point of manufacture, and with the ability to detect where packs may have been diverted from the legal supply chain. It is with this in mind that systems designers must interpret the relevant provisions and translate them into system specifications, technology choices, governance models and operational procedures that will result in an independent and secure track and trace system. In the course of doing so, system designers should, whenever possible, utilise proven technologies, leverage international generally accepted standards (e.g., ISO) and incorporate best practices.

2.1.3   *Proven benefits of Tracking and Tracing*

Traceability is critical in the fight against illicit trade: Experts agree that the single most effective solution to countering illicit tobacco is to better control the supply chain. Better controlling the supply chain requires knowing how many packs were made and declared for tax purposes. The benefits of introducing a traceability regime go far beyond complying with a provision of the Protocol – it offers tangible revenue and compliance results to governments and constitutes a sensible strategic priority for any agencies administering excise duties. It also supports the public health agenda and objectives related to cessation policies that utilise taxation to reduce smoking prevalence.

It must be noted that installing track and trace solutions and implementing the rest of the Protocol will not on its own guarantee the elimination of illicit trade, but puts Parties in a much more informed and prepared position to identify, combat and deal with illicit trade, as part of a set of comprehensive policies, particularly regarding changes in criminal legislation, and other supply chain policies included in Part III of the Protocol (like licensing, due diligence, record keeping).

There are numerous case studies that highlight the dramatic impact that a secure track and trace program can have. Some of the successes are included in Annex A (because they reference sites where solution providers have a commercial interest, the examples have been anonymised[8].) The benefits of introducing a traceability regime go far beyond simply complying with an obligation under the Protocol – they have the potential to be a significant revenue driver for governments, and even more so where they are combined with introducing traceability requirements for other excisable products like alcoholic beverages.

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[8] For a more comprehensive review see e.g.
http://www.unicri.it/topics/counterfeiting/anticounterfeiting_technologies/Ensuring_supply_chain_security_report.pdf

2.2 DEMYSTIFYING TRACK AND TRACE FOR TOBACCO PRODUCTS

One of the key challenges in respect of introducing a track and trace program as envisaged in Art.8 of the Protocol lies in the fact that it is often viewed as a new technology that is difficult to understand conceptually, and complex to implement in practice. In fact, the concepts around track and trace are reasonably straight forward, and we can find practical examples of where these concepts and technologies are already used in our daily lives. Most companies, particularly those involved in fast moving consumer goods (FMCG) have introduced some form of track and trace in relation to quality control, brand protection and supply chain management of the products they make. The technologies that underpin track and trace are in many cases already embedded in most of the world's supply chains. The global tobacco industry, however, has not yet embedded many of the practices and technologies employed by other manufacturers and today, tobacco supply chains remain comparatively opaque.

In the very simplest terms, track and trace combines two essential concepts. The first is tracking, which refers to the ability to monitor from the point of production through various points in the supply chain. The second, tracing is the ability to determine the point of origin of the product (where it was made). Tracking and tracing systems in relation to the Protocol involves applying a secure and unique mark on tobacco products that indicate "who" made them and "where" they were made, "which" market they were intended for, and to validate that the tax was actually paid. This involves putting a number – similar to a common serial number – on the pack that can be traced back to its original manufacturer and applying a set of security features that make it nearly impossible to copy or counterfeit. This is intended to ensure that both the product and the unique number are authentic (real/genuine). This embodies the core purpose of Art.8 of the Protocol– to ensure that governments know where cigarette packs came from, that taxes have been paid on them, and that they can trace illicit packs that may have come from known manufacturers, back to their manufacturing point.

There are four essential components that comprise track and trace:

1. **A Unique ID (UID)** – similar to a serial number;
2. **A security feature** – or set of security features – like the ones used for currencies and passports;
3. **A data carrier** – like a bar code or QR code – that provides the ability to capture supply chain events (movements and transactions) related to the products; and,
4. The ability to **authenticate** – a product to determine its status (e.g. is it genuine, is it in the market it was intended to be in and has the tax been paid).

As depicted in figure 1 the technologies employed for track and trace are quite common in today's modern supply chains and utilise existing technologies and methods. Thus, track and trace is not a new concept and almost all consumer goods have a barcode. The barcode serves many purposes – it plays a key role for manufacturers and their supply
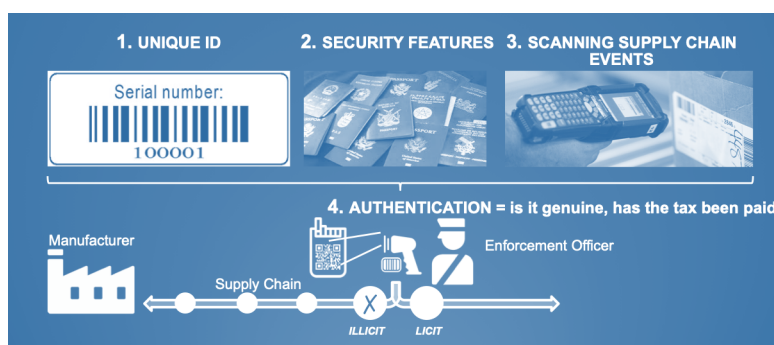

Figure 2: Track and Trace Technologies

chain partners to know exactly which products are where, almost anywhere across the globe, at any point in time. This makes it possible for them to better manage their supply chains in general, optimise the supply and demand of products and to effect product recalls of specific batches – something that is only possible by using tracking and tracing technologies.

Over time, the way traceability is used has evolved from the one-dimensional view of 'following' products to their source to a more robust view that incorporates brand protection and consumer awareness. Many manufacturers now use track and trace as a way to give consumers comfort that the products they are buying are legitimate, and not counterfeit, or to prove their provenance: from branded apparel with special hologram tags, to QR codes on expensive tubs of manuka honey, to codes on food packaging (even fresh fish) that allow consumers to see exactly where their food came from and that it was produced in a sustainable and ethical manner.

The tobacco industry already uses a form of track and trace to some extent: Some of the big tobacco companies have developed their own tracking and tracing solution which is used to mark some of their packs. However, to be clear the tobacco industry's solution, known as Codentify (and later re-branded as Inexto) is not fit for purpose to meet the obligations of the Protocol for several reasons. First, the software used was developed by the tobacco industry, and is currently deployed in some of their production facilities, and second, it is totally controlled by the industry, with almost entirely opaque business rules. It simply does not come close to meeting the obligations of Article 8.12 of the Protocol that states that "obligations assigned to the Party shall not be performed by or delegated to the tobacco industry".

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The tobacco industry has actively worked against efforts related to independent track and trace.[9] In contrast to other industries such as apparel, food, pharmaceuticals and many others, that have successfully implemented robust track and trace regimes. However, in the case of tobacco, track and trace is about both controlling the cigarette manufactures and following the tobacco products as they make their way through the supply chain for the simple reason that tobacco products are highly susceptible to illicit trade.
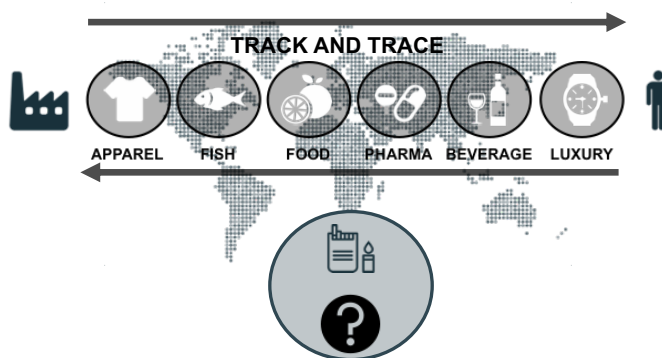
Figure 3: Track and Trace across Industries

Currently, misconceptions around track and trace include assumptions that it is difficult to implement, expensive and involves complicated and unproven technology, and that it will add countless costs and burdens to industry that will result in the loss of jobs and closure of factories. These myths have been disproved by countries that have already implemented key aspects of the Protocol successfully and by other industries that have proven the benefits of securing their supply chains[10]. Any notion that track and trace for tobacco products is too challenging is not a valid argument given the pervasiveness of track and trace across multiple industries.

2.3   EMERGING GOOD PRACTICE RELATED TO TRACK AND TRACE

2.3.1   Implementation Considerations

There is no one size fits all implementation as each country has a unique context in terms of its overall government structure and local illicit trade context. For example, in some countries the customs authority is responsible for the collection of excise whilst in others it is under the control of a revenue authority that may not also regulate cross border trade like customs. Additionally, the illicit trade context and associated risks can vary greatly as some countries do not manufacture tobacco products at all, others may be landlocked with no seaports and others may have imports, exports and local products of tobacco products.
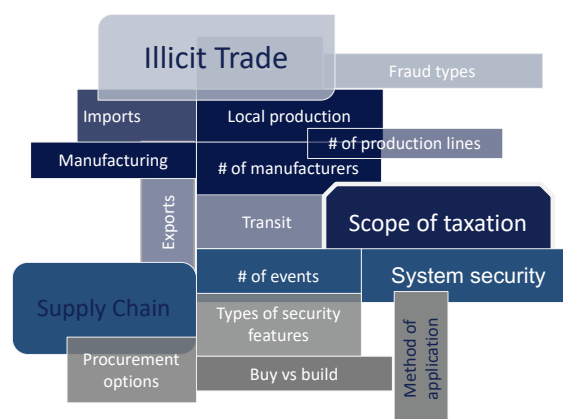

Figure 4 – Track & Trace Considerations

Although the technologies related to track and trace are not overly difficult or complicated, formulating a comprehensive illicit trade strategy that incorporates the needs of all key stakeholders (e.g., public health, revenue, law enforcement) is a significant endeavour and there is a lot that needs to be considered in order to maximise the benefits for all. For these reasons it is helpful to view the

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9 Gilmore AB, et al. Tob Control 2018;0:1–14. doi:10.1136/tobaccocontrol-2017-054191

10 Anonymised examples in Annexure A

Implementation of a track and trace solution as a journey that can involve multiple steps to ensure the solution is best fit for the local context. For example:

- **Step 1** -- An analysis of the existing environment to understand the nature of tobacco supply chains, identify enforcement gaps, agency capacity (e.g., strengths, weaknesses, gaps in terms of policy, human resources and technology) and highlight the specific requirements for a track and trace program to be delivered. This includes developing an overall strategy, governance model and a plan for delivery;

Figure 5 -- The Track and Trace Journey

- **Step 2** -- Once the environment is understood and the governance model is established the program can proceed to designing, which will include the concurrent establishment of a project delivery team, developing a motivated and defensible business case, technical specifications and the overall solution blueprint;
- **Step 3** – Commencing a "solution build" process which may involve activating a procurement process, selecting vendors, and/or deciding to develop the solution in-house.
- **Step 4:** Implementing the solution, which goes beyond being simply a procurement exercise, but focuses on integrating the solution with an agency's broader strategies, systems, processes and capacity to ensure that the agency has the practical ability to implement, administer and enforce the solution in the longer term.
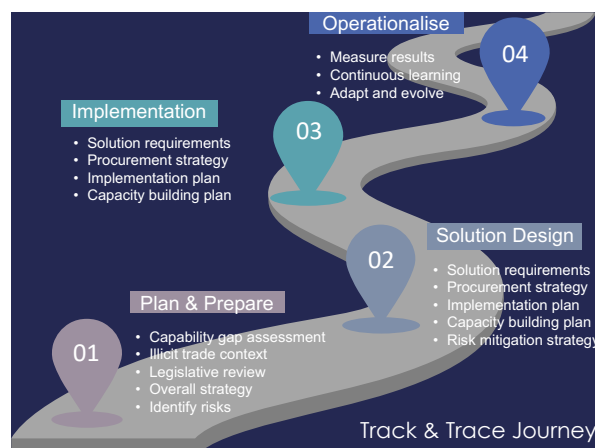
2.3.2   Strategic Design Principles

All large enterprise-wide systems require strategic guidance and track and trace is no different. The Protocol itself is a high-level instrument that does not contain sufficient detail from which to commence with a program and system specifications. Parties have many choices and options in terms of how to implement various provisions. The following design principles have been derived by the authors of this guide to serve as a guideline. This is based on the original intent of the Protocol and its origin and general good practice in terms of system implementation.

1) COMPLETE	Fully implement all the provisions within the Protocol;
2) CONSISTENT	Compatible with other national laws or regulations with respect to tobacco control (e.g., plain packaging);
3) INDEPENDENT	Completely independent of industry at all levels;
4) SECURE	Prioritise security and be highly resistant to circumvention and/or manipulation;
5) COMPETITIVELY SOURCED	Provide parties with the maximum choices in terms of both technologies and solution providers available;
6) COMPATIBLE WITH STANDARDS	Wherever possible utilise generally accepted standards;
7) PROVEN	Ensure that technologies and methodologies used should wherever possible have been proven effective in the tobacco domain;
8) PRACTICAL	Minimally invasive to the tobacco production and distribution environment in order to limit disproportionately impacting on industry;
9) COLLABORATIVE	Amongst key stakeholders and system users as well as with the Global Information Share Point;
10) FLEXIBLE	Adaptable to the changing illicit trade modus operandi as new solutions and technologies become available.

D E S I G N   P R I N C I P L E S

Figure 6: Strategic Design Principles

3 MAIN ELEMENTS OF TRACK AND TRACE

| Article 8.3 | *"each Party shall require that unique, secure and non-removable identification markings, such as codes or stamps are affixed to or form part of all unit packs and packages and any outside packaging of cigarettes…"* |

Track and trace involves the ability to securely identify a unique item, track its movement through the supply chain and the ability to determine its status (which market it was intended for, and whether tax has been paid etc.) and where it came from. This section of the guide will provide a summary of the key concepts related to implementing Art.8 of the Protocol as well as good practice recommendations based on proven technologies and methodologies that underpin track and trace. Figure 7 below depicts the core building blocks of secure traceability including:

- **A Governance Model** -- that places the Party and its lead agency (Competent Authority) in direct control of the track and trace solution;
- **Serialisation** -- using unique identifiers: Marking each item with a non-sequential unique code;
- **Security Features** -- that ensure to deter manipulation of the identifiers and make them less susceptible to fraud or tampering;
- **Data Storage & Management** -- to allow the Parties to query the database to ensure that tobacco products are licit;
- **Supply Chain Events** -- related to the movement of tobacco products; and,
- **Fraud Detection & Enforcement** -- within the supply chain.

Figure 7 - Track & Trace Building Blocks

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The International Organisation for Standardisation (ISO) has its own definition of traceability as the "ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component"- tracking is simply knowing where something originated and where it is intended to go, and tracing is knowing where it has been along the supply chain.

Traceability example:

To better understand traceability, consider a simple online sales transaction as an example (so, not related to tobacco, but perhaps for an order from an online retailer):
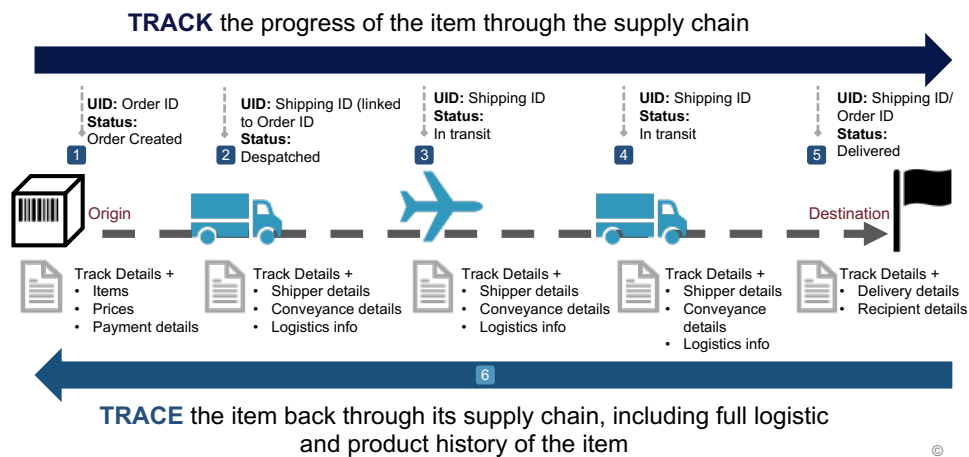
Figure 8: Traceability Example

1	The order is assigned a unique order ID within the system. The products are linked to that order and the items are parcelled.
2	Each parcel is assigned a unique shipping number that is applied on the label attached to the parcel. This will most likely contain a link to the order ID and other product or logistic information. It may also contain other information which is not confidential and readily accessible, such as brand description, place and date of production (as is also envisaged in Art 8.4). This information is also uploaded to the system.
3	This parcel is combined with other parcels, and the individual shipping numbers are linked to create a shipment. As the shipment (parcel) moves through the transport network to its destination, key events are recorded and uploaded by the logistics system at each stage, such as when the parcel arrives at a postal sorting centre or is dispatched on an aircraft.
4	By using either the order ID or the shipping number, any authorised party is able to track the location of the parcel at any stage and see how close it is to reaching its destination.
5	Once the parcel has reached its destination, the order information is updated, and the tracking process comes to an end.
6	As needed, on an ad-hoc basis following delivery of the item, an authorised party can trace the order, the route and time taken to deliver the parcel, and related production or parcelling information related to the order and the goods contained within. The trace capability remains open and available for as long as the system stores the related unique ID and related information.

Effectively, unique identification, serialisation, security features, supply chain event management and authentication enable secure tracking and tracing, which together equates to traceability[11]. These concepts are discussed in more detail below.

3.1 GOVERNANCE MODEL

A governance model is the mechanism used by the Party and its designated Competent Authority to translate the elements of the governance framework and policies into practices, procedures and defining the roles of key stakeholders. The Governance model defines "who" is in charge of the system and the relationship amongst the various role players. There is a very strong correlation between a governance model and the problem statement as the latter is a crucial determining factor in selecting an appropriate model and related attributes. Typically, governance models contain three key components:

1. **Oversight -** which establishes key roles and responsibilities, policies and procedures;
2. **Control -** which, in the case of the Protocol's requirements relies on various technologies (security features, data capture etc.); and,
3. **Validation -** that ensures that the overall system is checked, and that integrity is maintained over time.
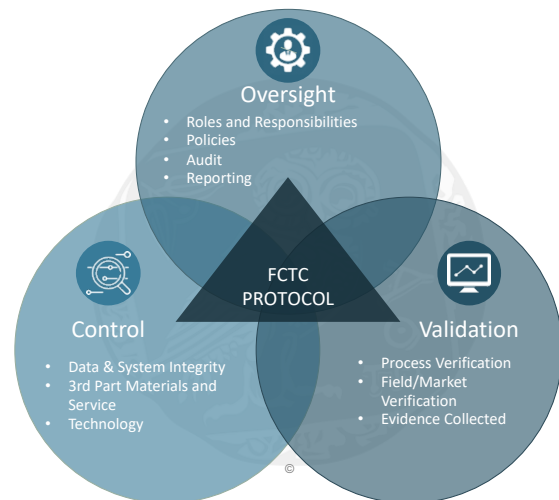
Figure 9 - Governance Model

Figure 9Figure 9 - Governance Model depicts a governance model for track and trace based on generally accepted good practice combined with key solution elements that would be required for effective implementation of the Protocol.

Given the nature of illicit trade and the track record of the tobacco industry a strong governance model is recommended for the track and trace solution. Key elements to consider when defining the governance model include:

- The Competent Authority should own and/or directly control the system via contractual relationships with solution vendors (if the solution is outsourced);
- The Competent Authority should insist that any solution vendors have no present or past conflict of interest when it comes to the tobacco industry and particularly with respect to the prior development of or participation in any solutions developed by the tobacco industry.
- The Competent Authority should have rights, privileges and remedies within any contracts related to the track and trace solution;
- The tobacco industry should have **no control** of any solution vendors contractually or financially as this represents a clear conflict of interest;

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[11] ISO 12931: 2012(E) https://www.iso.org/obp/ui/#iso:std:iso:12931:ed-1:v1:en

- The Governance model must incorporate clearly defined controls in terms of overall system integrity and security *inter alia* audits, anti-tampering measures in factories etc.;
- The role of industry should be limited to the extent of that which is necessary or required within the system (e.g., to understand tobacco supply chains) as obligations of the Party should not be "performed by or delegated to the tobacco industry"[12].

Establishing the right governance model is perhaps the most critical aspect of any track and trace solution given the tobacco industry's historical role with regard to illicit trade in general and their well-documented efforts and recent success in the European Union of infiltrating the process and successfully getting their proxies and historical allies as key solution vendors. According to a recently published paper, 'demonstrate that the tobacco industry has made concerted efforts to influence implementation of T&T in the EU and has been largely successful in maximising industry control and minimising independence of EU T&T[13].

3.2 UNIQUE IDENTIFIER (UID)

An identification code that is attached to an item or product which is **exclusive to that particular item**. This can be something like a serial number, or a numeric or alphanumeric code.

The unique identification number is often referred to as the "UID." A number may be unique in a particular market or country, or globally – in other words, there should not be another product with the same number.

The unique identifier must – by definition - be one of a kind. If two different items are marked with the same number (called an "identifier"), the system will suggest one product was in two different places at the same time. The design of the identifier therefore needs to consider the volumes of products in the market, and their active duration in the supply chain in order to ensure that codes are unique.

In terms of the requirements of Art. 8.1 of the Protocol, a pack marked anywhere in the world with a unique number should be distinct and distinguishable from all other packs around the world, regardless of producer, brand, type or country.

3.2.1 Serialisation

Serialisation ensures each item is **marked with a non-sequential, non-repeatable unique identifier** that prevents counterfeiting.

The unique code must be non-sequential and not predictable from looking at other codes – otherwise it would be too easy for an illicit trader to generate fictitious numbers. The codes are instead generated by a code generator that uses a mathematical algorithm to generate the unique codes in a "controlled random" manner.

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[12] Protocol to Eliminate Illicit Trade in Tobacco Products, Article 8.12

[13] Gallagher AWA, et al. Tob Control 2019;0:1–7. doi:10.1136/tobaccocontrol-2019-055094

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There are several technologies and methods available for adding a non-sequential, non-repeatable unique identifier to each product. There are numerous permutations possible, and all of which are already used for adding identifiers to other products beyond just tobacco, and which can be applied directly to packs or on labels. Whichever of the options in Table 2 is chosen, depends on the materials and packaging of the product, the level of security required, how the products will be tracked (human readable, machine readable or both), and cost. More sophisticated types of codes can of course have more detail embedded in them, and are more difficult to counterfeit, but are typically more expensive.

A simple alphanumeric code: A human readable combination of numbers and digits applied to the packaging (unsuitable for medium-to-high volume scanning / verification applications).	S-1F79C464-40C1-45B
A 1D barcode: Graphic representation of a unique code using structured combination of white and black bars. Highly machine-readable and often combined with a human readable component as a failsafe should the barcode be damaged.	0 123456 789012
2D barcodes: Datamatrix and QR Codes are examples of 2D bar codes that improve the amount of embedded data that can be stored, compared to the 1D barcode. 2D barcodes also offer improved resilience where data can still be read where part of the barcode is damaged. They are machine-readable only.	
RFID and NFC tags: These machine-readable tags use radio waves to communicate with a reading device. The tags contain an electronic chip that can store electronic data. RFID allows 1-way communication of data from tags to a single reader up to a 1m distance. Near Field Communication (NFC) is a new variation of RFID that allows 2-way communication between the reader and a single tag, but only up to (10cm). Pricing is becoming more competitive but remains relatively high.	

Table 1: Examples of Encoding Options

For the codes to be useful from a traceability perspective, they need to be linked to basic supply chain data (like date, place, time) and allow for additional data elements required for Art. 8.4.1. Some of the data contained in the unique identifier could be public and easily accessible, while other information may be confidential and only accessible by somebody with a special scanning device and access to a secure data base. (Think of a barcode on a tube of toothpaste – when it is scanned at a grocery shop cashier, the cashier's system knows that it is toothpaste, which brand it is, and what it costs. But the same barcode could also contain information on where the tube was made, and when, which would only be accessible to authorised individuals with the right equipment.)

3.2.2   The Concept of Aggregation

The whole point with traceability is being able to follow products as they travel through the supply chain. But of course it would be virtually impossible to scan every single individual pack of cigarettes as it leaves the factory, and then again as they are loaded onto different trucks, or offloaded at distribution centres, or pass through customs – the sheer volume of packs that would have to be unpacked and individually scanned would make it a near impossible task. Which is where aggregation comes in: in the simplest terms, it means that individual packs are associated with a larger container in the system. The packs are put into a master case, which gets its own identifier. That identifier is

linked on the system to all of the individual packs inside the master case, so that if that identifier on the master case is scanned, it provides a list of all of the individual packs inside it. The master cases are similarly packed into a pallet, which also gets its own identifier, and which is similarly linked to all of the master cases inside it. As a result, by simply scanning the code on the largest shipping unit (e.g., pallet or container), it is possible to see which master cases, and in turn which individual packs are inside it.

Aggregation ensures compliance with Art.8.3 which specifies "…unique, secure and non-removable 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…". This requirement extends the track and trace solution to cover the outer packaging of tobacco products in addition to the unit packs. In the case of cigarettes this would mean that every pack, carton, master-case, pallet and container must bear a UID to enable tracking and tracing.

Aggregation is a critical requirement for enforcement as it enables the tracing of multiple individual packs by reading the outer-package identifier, thereby negating the need to read every pack for authentication. The unique identifier on the container can then be used as a basis to record the movement of the container (and by implication all of its contents) through the supply chain. This establishes a parent-child relationship between each container and items in it, and can record the hierarchy between packs and cartons, cartons and master-cases, and master-cases and pallets, thus enabling a 'single-scan' access to all items linked via the aggregated relationship.

Pack level

Scanning at this level yields pack level traceability data.

Carton level (X 10 packs)

Scanning at carton level yields traceability data for the carton and all packs contained within.

Master-case level (X 50 cartons)

Scanning at master-case level yields traceability data for the master-case and all cartons and packs contained within.
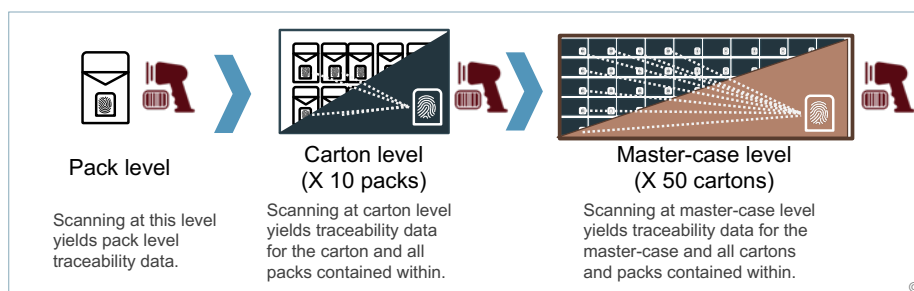
Figure 10: Aggregation Explained

As an example, a master-case, filled with 50 cartons of ten packs each may be received into a warehouse by scanning the code on the master case only. Aggregated information in the repository will reflect that all 50 cartons of cigarettes in the master-case have been received at the warehouse facility, and in turn each of the 500 individual packs. This means that logistic events can be recorded without scanning each individual pack.

The benefits of such an aggregated relationship is significant, especially from an enforcement perspective, where an officer or inspector only has a limited window of time and capacity to intervene on any container or package, whether at the border or at a warehouse. The ability to scan any pack, carton, master-case, pallet or container and determine the status of all items linked to that particular identifier significantly reduces the time required to conduct an inspection, reducing the time and cost burden on trade and the enforcement agency. It also significantly reduces the administrative burden on actors across the tobacco supply chain.

3.3   SECURITY FEATURES

> An overt or covert element placed on or within an item to deter duplication and/or deter manipulation or tampering. Security features **protect unique identifiers from being imitated or duplicated**.

While unique identifiers are an essential element of a track and trace system, they are not secure. Even if the UID incorporates encryption technology it is not immune from someone simply copying the code. In order to ensure the integrity of the identifiers that are applied, they are usually accompanied by a range of security features. As is the case with the unique identifiers themselves, there are a range of different types of security features that can be employed to complement the UID and establish a secure link between the two.

Security features provide a means to detect and combat attempts by criminals to manipulate the system, and a method to authenticate that the product and related markings are genuine.

A unique identifier on its own cannot assure authenticity, as valid codes could be used on illicit products. Without security complementing the uniqueness of the code, the identifier is just a set of numbers that, when queried, would not be able to identify a product as illicit. Regardless of the Protocol requirement for a secure and non-removable UID, this fact alone would compel Parties to include security features as a matter of course.

3.3.1   Choosing Security Features

Although security features come in various forms (e.g., inks, magnetic strips, holograms etc.) there are two key distinctions that need to be observed: those that are commercially available and are not subject to stringent supply chain controls (e.g., basic holograms), and can be bought by anyone; and those that are developed by specialist secure printers who tightly control who they sell their features to (currency, passports etc.).

Commercially available security features are normally used as part of commercial packaging by brand holders – but can be purchased by actors in the illicit supply chain. These are the security features of choice of tobacco manufacturers because they are generally very low in cost and can be incorporated into product packaging. While manufacturers are free to continue using these for their own purposes, these types of features are not recommended within the FCTC Protocol context simply because they are highly susceptible to copying and counterfeiting.

Instead Parties should only consider security features developed by specialist companies subject to rigorous controls of security features. Security features should be entirely independent from the tobacco industry and should be subject to robust supply chain controls during their manufacture, storage and transport. This minimises the risk of security features falling into the wrong hands and being made available for use in illicit trade.

3.3.2   Types of Security Features

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Security feature categories include[14]:

Category	Description	Example [15]
Overt	Security features that can be verified with the naked eye, such as colour changing inks, holograms, latent images, watermarks and security threads. They are useful tools for consumers and for quick marketplace inspections but are relatively easier to forge.	
Semi-Covert	Security features requiring a simple tool that does not require training such as UV fluorescent inks and specialised print techniques (e.g. microtext), and a simple device (e.g. UV torch).	
Covert	Security features that can be authenticated only by using a dedicated and specialised electronic reader for authentication, such as proprietary taggants or special invisible inks. They are more sophisticated by design and are far more difficult to counterfeit.	
Forensic	Security features including forensic markers identified through laboratory analysis providing irrefutable evidence that could be submitted as evidence in a court of law.	
Physical Security / Tamper Evident	Security features, including techniques to provide tamper evidence and elements to prevent transfer and reuse. These could include frangible paper with micro-cuts, which tear if somebody tries to tamper with the mark and make it virtually impossible to remove the mark without damaging it.	
Digital Fingerprinting	Security features using material fingerprinting and entropy-based / chaometric authentication techniques. These can include visible elements which provide covert and semi-covert elements which require specialised techniques to authenticate.	

Table 2: Security Feature Categories

3.3.3 Layering of Security Features

Because counterfeiters have become so adept at what they do, all good security documents (bank notes, passports, tax labels) use what is called "security layering[16]." This entails combining multiple types of security features which dramatically increases the challenge to potential counterfeiters and illicit traders – because there is more than one security feature, it makes it more costly to copy, and therefore increases the barrier of entry to potential fraudsters.

By layering security features, access can also be controlled for different users (e.g. consumers, distribution chain operators, enforcement authorities) and also increase security so that no one party has access to all the elements[17].

In recent years, an additional layer comprising information security has also been added, including encryption and online verification techniques to increase overall security.
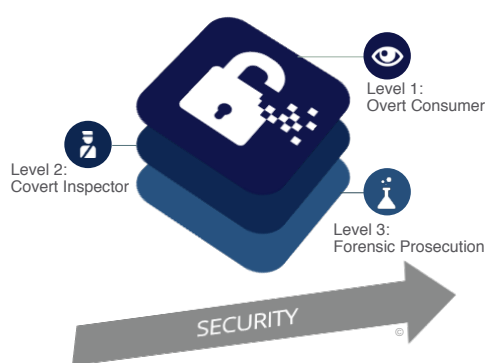

Figure 11: Layering of Security Features

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[14] For further detail on security feature types refer to Annex 3: Types Of Security Features

[15] Image sources: http://www.prooftag.net/, http://www.labellock.com/, http://banknotes.resbank.co.za/, http://www.eltronis.com/

[16] ISO 12931: 2012(E)

[17] ISO 12931: 2012(E)

(Encryption is simply about encoding a message or information in such a way that only authorised parties can access it making the content unintelligible for somebody who does not have the decryption key. It is a bit like needing the Rosetta stone to decipher ancient Egyptian hieroglyphs.

3.3.4   Application Method for Security Features

Art. 8.3 stipulates that "*unique, secure and non-removable identification markings such as codes or stamps are affixed or form part of all unit packets and packaging*" for tobacco products. The options available to comply would be:

- **Direct printing** which involves printing the unique mark directly onto the finished pack, normally using standard or security ink. This method does come with limitations in terms of the overall number and types of security features that can be used. It essentially limits the field of security features to those that can physically be printed on packs and is considerably restricted in terms of the robustness and the number of security features available. There are also limitations in terms of printing and manufacturing line speeds.

- **Affixing** the mark as part of a separate label. Using a separate label or "stamp" has several advantages in terms of the overall number of options that can be employed and the wide choice of independent security feature providers. Using a label (similar to a tax stamp) offers the best option overall in terms of meeting the requirements (figure 9).

	Printed Directly onto Product	Finished Label applied on Product
Range of security feature options	▂ (1/4)	▅ (4/4)
Combined security strength (Overt, Covert & Forensic)	▂ (1/4)	▅ (3/4)
Irremovable	▅ (4/4)	▅ (3/4)
Provides volume verification (to reconcile with traceability)	▅ (3/4)	▅ (4/4)
Controlled supply chain	▅ (3/4)	▅ (4/4)
Number of market providers	▂ (1/4)	▅ (3/4)
Impact on packaging design	▃ (2/4)	▅ (3/4)
Compatibility with tobacco flows (high speed, low volume, imported/exported)	▃ (2/4)	▅ (4/4)
Minimised impact on production line	▃ (2/4)	▃ (2/4)
Indicative (low) cost comparison	▃ (2/4)	▅ (3/4)
OVERALL	▃ (2/4)	▅ (3/4)

Table 3: Security Feature Application Methods

3.3.5   Non-removable (tamper evident)

Ensuring that a security feature cannot be removed and reused is important. It is also critical that marks are destroyed or damaged during any attempts at tampering. Security features should

therefore be both resistant to tampering in the first place but also provide evidence that tampering has been attempted. Some technologies and methods including using stamps that are made with frangible paper (tiny micro cuts that destroy the stamp if it is removed).

"*Non-removable*" as contemplated in Art. 8.3 relates to tamper resistant elements of the security feature. ISO 12931: 2012(E) defines tamper resistance as "*the ability of the authentication element to resist the removal, alteration or substitution of the element from the material good or its packaging.*" Tamper resistance is only one of the elements the ISO standard identifies as a means for "*attack resistance*". Other attack resistant elements include resistance against reverse engineering, copying, alteration, side channelling, interception of communication between the security feature and any authentication tool, obsolescence and uncontrolled reuse.

3.4   AUTHENTICATION

Authentication	The ability to verify the authenticity of a product using the unique identifier and validate the integrity of the item using the security features to provide a high confidence level that the unique identifier and product is valid.

Enforcement agencies play an important role in managing compliance levels of manufacturers and distributors. As available enforcement resources are limited, the security feature should make inspections of the supply chain as quick and efficient as possible, whether at the border, in the distribution chain or during inspections in the retail market. The security feature should also support a consumer's or retailer's ability to easily authenticate the security feature without requiring specialised equipment. As discussed in the prior section this "overt" authentication is not as secure as other types of features and should be coupled with more robust features that can be used by law enforcement and that can be used for court admissible evidence.

There are different authentication devices available, according to the level of authentication that needs to be provided, and to which user(s). For example, consumers and retailers would not verify authenticity at the same level as enforcement officers who would need more robust and specialised tools to access more sophisticated security features.   As such there are different types of authentication devices which range from simple devices like lenses to more advanced tools such as specialised smart phone apps. Forensic features require the use of specialised laboratory equipment. The ability to verify forensic features should be under the control of the Party and/or its designated Competent Authority and should under any circumstances rely on the tobacco industry for verification. The Party or Competent Authority can either conduct forensic analyses themselves (in-house) or have this capability outsourced to an independent laboratory or via the provider of security features.

Targeted User	Feature	Description
Consumers	Eye	Overt security features can be verified by any user as a first level of authentication. It relies on physical security which is visible with the naked eye.
Consumers	Mobile Phone	Increasingly more security features incorporate a security element that can be verified using mobile phones, providing information about the product and its origin.

Supply chain, enforcement	Filters, magnifiers, UV lamps	Provided to supply chain stakeholders, as well as enforcement officials, to verify semi-covert security features.
Enforcement	Yes/No devices	Provide immediate answers to field officers (a simple Yes/No indicator) on the presence of specific covert markers in the security feature, making it possible to immediately distinguish between licit and illicit products.
Enforcement	Dedicated electronic device	Only provided to enforcement officials, they provide further security and are more reliable than mobile phones as they feature specific functionalities allowing further information for enhanced verification. These devices can take various forms, and can include PC accessories devices (e.g. readers, scanners or microscope cameras), add-on hardware for mobile commercial devices, or self-contained proprietary hand-held devices.
Legal procedures	Laboratory equipment	Dedicated and specialised equipment used for the detection of forensic markers. This is used mainly to secure additional indisputable court-admissible evidence in case of legal procedures.

Table 4: Authentication Users and Authentication Devices

3.5 DATA MANAGEMENT

The foundation of any traceability solution lies in the ability to capture, store, interrogate, analyse and report on the data that is captured through the lifecycle of a product along the supply chain. In the case of tobacco products, the volumes are very high, and the data management system may have to be able to handle billions of products and all the track and trace data associated with them. Thus, the data management system not only has to be robust enough to handle very large volumes of data, but it also must be accessible to enforcement officers and other regulatory bodies when they require it. The data must also be secure so as to protect sensitive commercial data and only be accessible to those that are authorised.

TRACEABILITY DATA MANAGEMENT

Secure | High Volume | Available
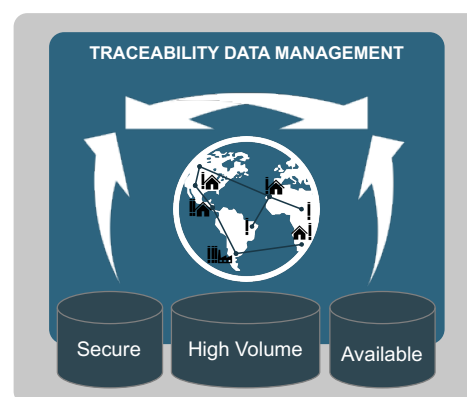
3.5.1 Requirements for Data Management

The selection of the proper architecture and underlying technologies should consider a number of data management characteristics, explored in the table below and dealt with in more detail in the following sections.[18] (Some of the terms are relatively technical, but a simple high-level understanding of the key concepts is sufficient.)

Requirements of Traceability in the Tobacco Domain		Data Management Characteristics
High Volumes	→	High Cardinality (referring to the number of units requiring tracing)
Field Enforcement	→	High Availability (Data needs to be available for query as and when required)

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[18] For further detail refer to Annex 4.

Multiple/Dispersed Locations	→	Distributed by Nature (de-centralised and made available where required)
Sensitive and Proprietary Data	→	Sustained Data Ingress/Egress (referring to the control and networking of inward and outward movement of data)
Multi-system Operator Solutions	→	Security
Fraud Detection	→	Master Data Management (MDM) Interface & Serial Generation
High Volumes	→	Monitoring, Inconsistency Detection & Reconciliation

Table 5: Data Management Requirements

3.5.2 Information Sharing

Art.8.1 of the Protocol specifies *"…a global tracking and tracing regime, comprising national and/or regional tracking and tracing systems and a global information-sharing focal point located at the Convention Secretariat of the WHO Framework Convention on Tobacco Control and accessible to all Parties, enabling Parties to make enquiries and receive relevant information*." Further to this, Art.8.9 requires that Parties maintain confidentiality according to national law but grant reasonable query access to parties requesting information for detecting or investigating illicit trade, typically as part of law enforcement and investigations functions.

The Protocol has not specified the means or manner of achieving such a global information sharing point leaving it up to Parties to define how they would enable this requirement. (In other business cases where data-sharing is imperative, international standards for the structuring and coding of data are often used, such as those contained in ISO standard 16678:2014[19].) National systems may not need to directly communicate with each other, but the data produced should be structured and stored in such a way that it can be queried from outside the national track and trace system.

3.5.2.1 Standards for Sharing Data

Recording track and trace events across an entire distribution chain means events may be captured by different organisations using different systems. A traceability solution therefore needs to include a way for all this event information to be accumulated to support tracing queries and supply chain oversight, and for users of different systems to still seamlessly share data. In the simplest terms this could be done through what can be thought of as an "interface layer" – something that makes data from one system readable in another one.

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[19] https://www.iso.org/standard/57391.html

Several industry standards have evolved relating to the marking methods used, the capture, storage and sharing of track and trace events. Of particular interest is the Electronic Product Code Information Service (EPCIS), a technical standard promoted by EPCglobal (part of the non-profit industry organisation GS1.) It provides a data model and interface specification for product movement events of uniquely identified objects in general but has become a *de facto* industry standard for recording supply chain events in virtually all industries and categories of products. These standards and EPCglobal-certified event repositories also allow interoperability between systems sharing track and trace information. In 2015, the ISO recognised EPCIS as a standard to enable disparate applications to create and share visibility event data, both within and across enterprises[20].
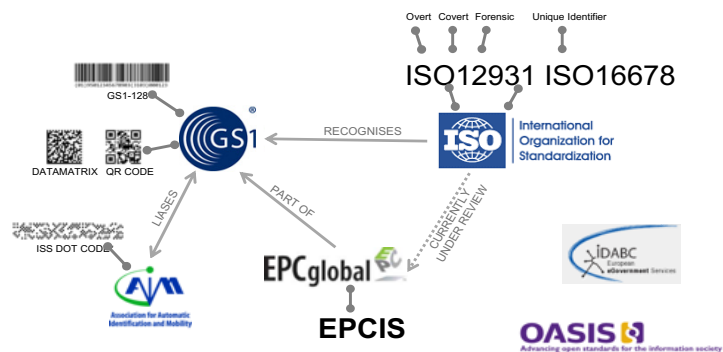
Figure 12: Example of Standards and Bodies

EPCIS provides a standard for enabling the "**Who, What, Where, When,** and **Why"** of events occurring in any supply chain to be exchanged, safely and securely. That includes information such as the time, location, intent and business step of each event that occurs during the life of an item in the supply chain.

In sum, the GS1 standard offers a framework to establish a holistic view of the supply chain and create a bridge between physical goods and the information flow, regardless of what systems users may have, and is already widely in use in the tracking of goods across supply chains. Its neutrality and general acceptance make it well positioned to appropriately respond to traceability system design and implementation requirements. EPCIS has been implemented and is supported by several software providers including the likes of IBM, Microsoft, Oracle, SAP, NEC, LG, as well as Fosstrak, an open source software project.

3.6   SUPPLY CHAIN EVENTS

There are a number of supply chain events that could be required for tracking and tracing depending on the scope of obligations imposed on the customs and excise agency. Based on the stipulated scope, and utilising a standardised format as mentioned above, supply chain events would need to be recorded and uploaded to the data repository or stored locally by each entity. Depending on the existing infrastructure and processes some changes may be needed by supply chain operators to ensure compatibility with the standard.

During movement of products through the supply chain, the exit of packs from the possession of one supply chain operator happens simultaneously with possession of the next operator. For example, tobacco products on wrapped pallets are stored in a manufacturer's warehouse awaiting transport by

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[20] https://www.iso.org/standard/66796.html

a logistics provider to the customer. The order is staged in the dispatch area, and once the truck arrives, the pallets are immediately loaded onto the truck. During this loading operation, the barcode of each pallet is read to record its unique identifier and to associate it with the dispatch event that will be reported by the manufacturer.

Following this logistics event there are three possible traceability information density levels:

A. **Dispatch Events from Facilities:** A traceability record is submitted by the manufacturer or warehouse operator at the time of dispatch, indicating the intended destination and the transporter. With this level of granularity, there would hypothetically be no further obligation on the transporter to report the movement, or on the receiving party to report the receipt of the tobacco products;

B. **Receipt & Dispatch Events between Facilities:** A traceability record is submitted by the manufacturer or warehouse operator at the time of receipt and dispatch of tobacco products. Dispatch events would include indicating the intended destination and the transporter (logistics provider); or

C. **Receipt, Dispatch, Movement and Transport Events:** At this level, in addition to the events described in level B above, the logistics provider scans the items received for transport. This would have to happen almost simultaneously, as the manufacturer scans the items to record their dispatch.
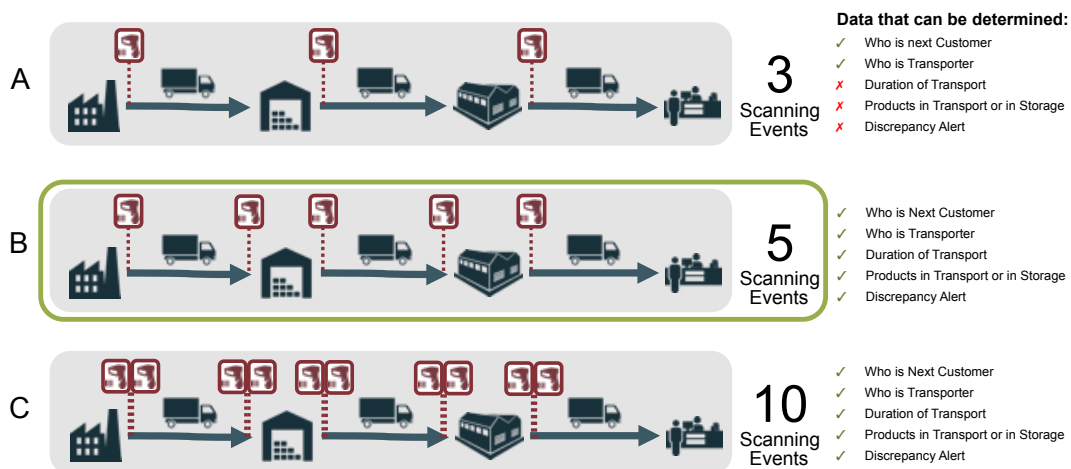
Figure 13: Supply Chain Event Scenarios

Level B provides a balance of process efficiency and proportionality of the supply chain impact and information controls.

Governments would need to decide their specific requirements based on the risks they are trying to circumvent and bearing in mind the significant impact this requirement could have on supply chain operators – more scanning events provide more security, making it possible to identify exactly where in the supply chain packs were diverted into the illicit supply chain. However, requiring for example, that a consignment be scanned twice for one event (packs being loaded onto and off loaded from a truck) would probably be an unnecessary additional burden with limited benefit).

Superimposing the above concepts and principles onto a typical tobacco supply chain consisting of three main components, production, distribution and retail can be depicted as in **Error! Reference source not found.**12 below:
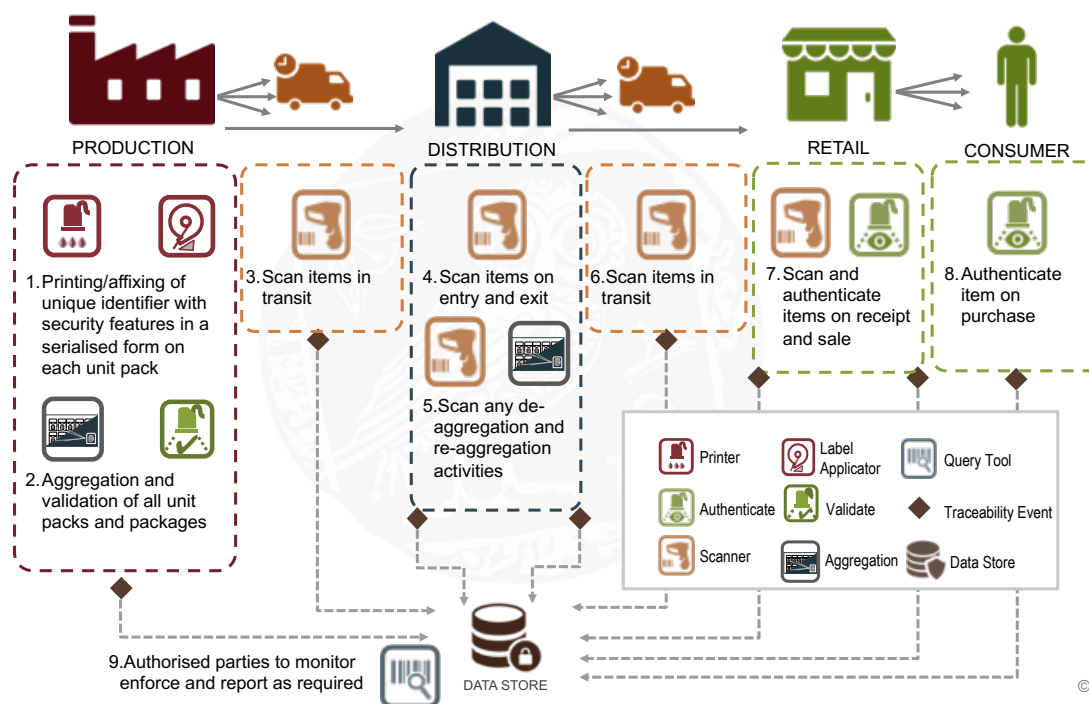
Figure 14: Tobacco Traceability Solution

4   TRACK AND TRACE CHECKLIST

The following checklist encompasses a good practice across the spectrum of the core building blocks for track and trace. It should serve as guidance to Competent Authorities to ensure the solution is independent of industry, is aligned to the intent and principles as set out in the Protocol and is best fit to combat illicit trade.

GOOD PRACTICE CRITICAL SUCCESS FACTORS	✓
Governance Model	
▪ The Competent Authority should own and/or directly control the system via contractual relationships with solution vendors (if the solution is outsourced).	☐
▪ The Competent Authority should insist that any solution vendors have no present or past conflict of interest when it comes to the tobacco industry and particularly with respect to the prior development of or participation in any solutions developed by the tobacco industry.	☐
▪ The Competent Authority should have rights, privileges and remedies within any contracts related to the track and trace solution.	☐

▪ The tobacco industry should have no control of any solution vendors contractually or financially as this represents a clear conflict of interest.	☐
▪ The Governance model must incorporate clearly defined controls in terms of overall system integrity and security inter alia audits, anti-tampering measures in factories etc.	☐
▪ The role of industry should be limited to the extent of that which is necessary or required within the system (e.g., to understand tobacco supply chains) as obligations of the Party should not be "performed by or delegated to the tobacco industry"[21].	☐
Unique Identification	
▪ The unique identifier is generated and secured by a party independent of industry (e.g., the Party itself or a designated 3rd party service provider contracted directly to the Competent Authority).	☐
▪ The unique identifier contains or can provide as a link the information as prescribed in Art 8.4.	☐
Serialisation	
▪ The unique identifier is non-sequential, non-predictable and non-repeatable and can be applied to every unit of product.	☐
▪ The method of application considers materials and packaging of the product, the level of security required and how the products will be tracked.	☐
▪ Solution includes aggregation to establish relationships between units of packaging (e.g., pack, carton, master case, pallet, container).	☐
Security Features	
▪ The competent authority (Party) and not the tobacco industry should stipulate which security features should be used and where they may be sourced from.	☐
▪ Security features should be sourced from independent (of the tobacco industry) security feature providers, that comply with relevant standards.	☐
▪ Security features should be combined (layered) in order to minimise the risk of duplication/imitation.	☐
▪ Security features should be evaluated from time-to-time and rotated in order to deter the potential for counterfeiters to attempt to imitate such features.	☐

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[21] Protocol to Eliminate Illicit Trade in Tobacco Products, Article 8.12

▪ The competent authority must maintain the ability to independently authenticate security features. This should not be delegated to the industry.	☐
Authentication	
▪ Products can be authenticated overtly, covertly and forensically.	☐
▪ Authentication can be done using simple, easy-to-use device for consumers and more sophisticated devices for enforcement.	☐
▪ Forensic features should be authenticated by the Competent Authority or a designated third-party independent of the tobacco industry.	☐
Data Management	
▪ The data management system caters for specific tobacco domain requirements with regards to cardinality, availability, security, etc. (As detailed in section 7.1 above).	☐
▪ The data management system utilises standards for data exchange that enables widespread uploading and sharing of all supply chain event data.	☐
▪ Provider has proven highest standards for security and data integrity.	☐
▪ Data management system has a fail-over and back-up solution in place to avoid production down-time.	☐
Supply Chain Events	
▪ Sufficient scanning events take place in order to collect all relevant information	☐
▪ Balance of process efficiency and proportionality of the supply chain impact and information controls	

5 ADDITIONAL SUPPLY CHAIN SECURITY MEASURES REQUIRED UNDER THE PROTOCOL

While the introduction of a track and trace regime for tobacco products is a critical component to secure the supply chain, it is not the only one. Other good practices are referenced in the Protocol which are equally important, and which can be implemented independent from track and trace solutions. These are referenced in table 6 below:

Article	SUMMARY OF ADDITIONAL SUPPLY CHAIN-RELATED PROVISIONS
Article 6 : Licensing	• Manufacture, import and exports of tobacco products and manufacturing equipment requires a licence • Licensing conditions should include providing information on identify, location of premises, products manufactured, equipment used, previous criminal records,

	banks accounts to be used, intended market of sale which includes showing that manufacturing is commensurate with reasonably anticipated demand.
	• Audit licences to prevent, detect and investigate fraudulent practices
	• Periodic reviews, renewals and audits of licences
	• Expiration of licences and reapplication processes
	• Notification of change of location or activities
	• Reporting of the acquisition or disposal of manufacturing equipment
	• *May* choose to licence retailers, growers, transporters, wholesalers, brokers, warehousing
	• [to be augmented by further research to assess whether key inputs into the manufacturing process – line filters and paper – can be subject to effective controls, after which this may be further strengthened]
Article 7: Due diligence	• Everybody in the supply chain must conduct due diligence before commencement and during course of business relationships, which includes know-your-customer requirements, monitoring sales to ensure quantities are commensurate with demand in the intended market of sale, and reporting any evidence that a customer contravenes its obligations
	• Due diligence may include requiring customers to declare criminal records and provide details of bank accounts,
	• *May* designate certain customers as "blocked customers"
Article 9: Record keeping	• Provide complete and accurate records of all transactions which includes full accountability for all materials used in the production of tobacco products
	• Provide on request information on market volumes, trends, and forecasts, and on quantities of tobacco products and equipment
	• Provide information on tobacco products and manufacturing equipment at the time when the goods depart from their control status [with a comprehensive list of information required detailed in art. 9.3]
	• All records to be maintained for at least 4 years, and kept in the format prescribed
	• *May* require retailers and tobacco growers to maintain complete records of all transactions
Article 10: Preventive measures	• Require all persons to take necessary measures to prevent diversion of tobacco into illicit channels including reporting the cross-border transfer of cash and cross-border payments in kind; and supplying tobacco only in amounts commensurate with the demand in the intended market of retail sale

	• Payments may only be made in the currency and the same amount as the invoice, and only using legal modes of payment from financial institutions in the intended market and may not be made using any alternative remittance systems. • Criminal, civil or administrative procedures and effective proportionate dissuasive sanctions including suspension or cancellation of licences • *May* require that payments for materials used in the manufacture of tobacco products may only made in the currency and the same amount as the invoice, and only using legal modes of payment from financial institutions in the intended market and may not be made using any alternative remittance systems.
Article 11: Internet sales	• All internet-, telecommunication-, or other technology-based modes of sale must comply with all of these obligations' • *May* ban the retail sale of tobacco products through internet-, telecommunication-, or other technology-based modes
Article 12: Free trade zones and transit	• Effective controls on all manufacturing of and transactions in tobacco and tobacco products in free zones using the measures in the Protocol • Prohibiting the intermingling of tobacco products with non-tobacco products in a single container or other similar transportation unit is prohibited at the time of removal from a free zone • Apply control and verification measures to transit or transhipment of tobacco products and manufacturing equipment to prevent illicit trade
Article 13 : Duty free sales	• Duty free sales are subject to these provisions • [to be augmented by further research into the extent of illicit trade related to duty-free sales, after which this may be further strengthened]
Article 14 : Offences	• Adopt measures to criminalise a series of conduct based on the provisions above [with a comprehensive list of information required detailed in art. 14]
Article 19: Investigative techniques	• Use of controlled deliveries and other special investigative techniques like electronic surveillance and undercover operations (in accordance with domestic law) • Leveraging bilateral or multilateral agreements or arrangements

Table 7: Other Obligations Under the Protocol

From the supply chain perspective, the Protocol's requirements can be simplified to five key areas as depicted in Figure 15 below: production of raw tobacco, manufacturing, supply chain security, government enforcement policies and regulation of sales. (Some of the requirements are peremptory – the ones that are optional are denoted with the preface "may," and are denoted in grey in the diagram.)

SUMMARY OF KEY PRINCIPLES

MANUFACTURING

- All manufacturers, importers, exporters of tobacco or equipment *must* be licensed
- Licenses must be audited and renewed
- Complete records: account for all inputs used
- Free trade zones must comply

SUPPLY CHAIN SECURITY

- May choose to licence transporters, brokers, warehousing
- Tracking and tracing system, controlled by Party, up to point where duties are discharged – may not be delegated to tobacco industry
- Take necessary measures to prevent diversion of tobacco into illicit channels
- No intermingling of tobacco in containers
- Controlling transhipments

PRODUCTION

- May choose to licence growers
- May require growers to keep records

GOVERNMENT

- Criminalise non-compliance
- Destroy confiscated tobacco and manufacturing equipment
- Use special investigative techniques
- Cooperation, information sharing, reporting

SALES

- Due diligence: Must introduce know-your-customer requirements and commensurate demand calculations
- Payments only in same currency and same amount as invoice and only using legal modes of payment
- All duty-free sales, and internet-based sales must comply
- May choose to licence retailers and wholesalers
- May ban retail sale on internet
- May require retailers to keep records

Figure 15: Summary of Key Principles of The Protocol

6   ANNEXURES

	ANNEX A -- EXAMPLES OF SUCCESSES ACHIEVED (ANONYMISED DATA) BY SEVEN DIFFERENT COUNTRIES
1	Enabled government to collect $2,000,000 in additional taxes
2	Increase in government revenues on tobacco products of $1.8 billion. Estimated government budget on excise revenues from tobacco and alcoholic products increased by 85% in the first year and by 94% in the second.
3	Increase in revenues collected of 15,000,000 Euros during the first 2 years of application A 61% reduction of smuggling
4	In the first three months of operation, government collected $90 million more in tobacco excise tax revenue than forecasted. Five manufacturing sites with undeclared or illegal production were shut down. In the space of two years, tax revenue increased by 24% and illicit trade reduced by 6%
5	Seizure of more than 350,000 illicit products; 100% prosecutorial success in more than 400 criminal cases; Increase in excise revenue collections of 53%.
6	Over $2 million of additional revenues in fines and recovered excise taxes collected.
7	Government revenues from taxes paid by manufacturers and importers of marked goods increased by more than $1 billion. The number of legitimate manufacturers increased from 210 to 250. The number of registered importers from 6,600 to 9,800.

7   ANNEX B -- GLOSSARY OF TERMS

- **1D Barcode -** Graphic representation of a unique code using structured combination of white and black bars. Highly machine-readable (most cases irrespective of orientation) and often combined with a human readable component as a failsafe should the barcode be damaged or result in errors when reading.
- **2D Barcode** – A machine-readable code that allows data to be encoded in a matrix of binary cells compatible with most printing techniques. Increases the amount of embedded data that can be stored as compared to the 1D barcode. 2D barcodes often can employ redundancy techniques where data can still be read where part of the barcode is damaged / destroyed. These barcodes are machine-readable only (human readable codes may be printed alongside or beneath).

- **Aggregation** - Allows for the identification of each of the items within a container to be recorded and associated with a unique identifier that is then assigned to the container.
- **Alphanumeric Codes** - A human readable combination of numbers and digits applied to the packaging. Machine readability can be problematic making this unsuitable for medium-to-high volume scanning / verification applications.
- **Application Identifier (AI)** – used as part of the GS1 standard to identify the data type of field encoded within a data barcode (variable information, such as a batch number, production date or customer purchase order).
- **Authentication** - Process of determining whether someone or something is, in fact, who or what it is declared to be (the genuine article).
- **Competent Authority** – A government agency designated by the Party (government) to implement the track and trace solution.
- **Counterfeit** - to simulate, reproduce or modify a material good or its packaging without authorisation.
- **Covert Authentication** - Not instantly recognisable or interpretable by the human senses but requires authentication tools and/or specialised knowledge to verify their presence and validity.
- **Data Matrix** - Two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or numeric data.
- **Data Repository** – Database used to store all traceability events and related data related to a tobacco item.
- **Direct Marking** – Method of applying codes and barcodes directly to product.
- **Distributor/Agent** - Major wholesaling companies have local agents (normally small businesses) that sell and deliver tobacco products to retail shops
- **Electronic Product Code Information Service (EPCIS)** - Technical product code standard promoted by GS1 (formerly EPCglobal).
- **Enterprise Resource Planning (ERP) -** Ability to deliver an integrated suite of business applications. ERP tools share a common process and data model, covering broad and deep operational end-to-end processes, such as those found in finance, HR, distribution, manufacturing, service and the supply chain.
- **Enterprise Service Bus (ESB) - S**oftware architecture model used for designing and implementing communication between mutually interacting software applications in a service-oriented architecture (SOA).
- **EPCglobal** – Part of GS1 since 2011, provides a data model for product movement events of uniquely identified objects in general. Whilst originally developed for the RFID industry, this data model has become a standard for recording supply chain events. These standards and EPCglobal-certified event repositories allow interoperability between systems sharing track and trace information. It should be noted that GS1 EPCglobal has a separate board of governors from the GS1 Management Board. All standard development and maintenance activities that used to be managed by EPCglobal were transferred to the Global Standard Management Process (GSMP) governed by GS1
- **Excise Tax Stamps –** Stamps or labels placed on individual products to indicate that relevant excise duties have been paid.

- **Forensic Security Feature** – Feature identified through laboratory analysis and provide proof of authenticity that can be used for evidence submission in a court of law.
- **GS1** – Organisation that has the most widely used global standards to improve the efficiency of supply chains globally across sectors. This includes standards for barcodes, data-matrices and unique product identifiers.
- **Illicit Whites** - Cigarette brands, produced in an open manner at well-known locations, which are mainly intended for the illegal market in another country. These 'cheap whites' or cigarettes are produced (often legitimately) in their country of origin at a very low cost and are destined to be illicitly sold in other jurisdictions where they do not meet the legal requirements.
- **Import of tobacco or related products** means the entry into the country of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry, as well as their release from a customs suspensive procedure or arrangement;
- **Importer of tobacco or related products** means the owner of, or a person having the right of disposal over tobacco or related products that have been brought into the country.
- **International Standards Organisation (ISO)** - an independent, non-governmental membership organisation and the world's largest developer of voluntary International Standards.
- **Manufacturer** - Any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under their name or trademark.
- **Master Data Management (MDM)** - Technology-enabled discipline in which business and IT work together to ensure the uniformity, accuracy, stewardship, semantic consistency and accountability of the enterprise's official shared master data assets.
- **Master-cases** – a shipping unit of tobacco products, usually containing 25 or 50 cartons of cigarettes
- **OASIS** – Organisation that develops and promotes a number of open standards relating to inter-system messaging and system security. In the context of a track and trace system, supports for open standards increases the interoperability with other systems and is essential in a domain where system integration with public and private information systems is critical.
- **Optical Variable Device (OVD)** is a security element that exhibits various optical effects such as movement, hidden images or colour change effects. These properties mean OVDs cannot be photocopied or scanned and employed to resist replication.
- **Other Tobacco Products (OTP)** refers to tobacco products other than cigarettes including cigars, smokeless tobacco and roll-your-own tobacco.
- **Outside Packaging** means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging.
- **Overt Authentication** - Authentication element which is detectable and verifiable by one or more of the human senses without resource to a tool (other than everyday tools which correct imperfect human senses, such as spectacles or hearing aids).
- **Overt Security Features** – Features that can be verified by naked eye, such as colour changing inks, holograms, latent images, watermarks and security threads.
- **Product Serialisation** (or mass serialisation) is the process used by manufacturers to assign and mark each of their products with a unique identifier.

- **QR Codes -** Machine-readable code consisting of an array of black and white squares, typically used for storing URLs or other information for reading by the camera on a smartphone.
- **Relational Database Management System (RDBMS) -** Database management system that is based on the relational model as invented by E. F. Codd, of IBM's San Jose Research Laboratory.
- **RFID and NFC Tags** - Machine-readable tags use radio waves to communicate with a reading device. The tags contain an electronic chip that can store electronic data. The radio waves emitted by the tag-reading device powers the chip, allowing data to be transmitted wirelessly, even where there is no line-of-sigh (with some restrictions) Radio Frequency Identification (RFID) has become more pervasive & allows 1-way communication of data from multiple tags to a single reader up to a 1m distance. Near Field Communication (NFC) is a new variation of RFID that allows 2-way communication between the reader and a single tag, but only up to (10cm). Pricing has become more competitive but remains relatively high compared to other marking methods.
- **Secure Mark –** Text or symbology (e.g. data matrix) that uniquely identifies a product item that is applied to the product using a security feature / security printing technique with the intention of preventing unauthorised parties from applying or manipulating the text or symbology or replicating the secure mark onto other items.
- **Security Layering -** Combining multiple security features and dramatically increasing the challenge to potential counterfeiters and illicit traders.
- **Semi-Overt Security Features – Security** features requiring a simple tool and minimal training to authenticate the security element.
- **Serialisation –** ensuring each and every item is marked with a unique identifier. This provides the basis to monitor and record the existence, location, and associated events of that item from the moment the mark is applied, potentially through its use / consumption lifecycle.
- **Service Level Agreements (SLA)** are part of a contract where a service is formally defined. Particular aspects of an acceptable minimum service - scope, quality and responsibilities - are agreed between the service provider and the service user (e.g. a response to a logged helpdesk request will be provided within 4 hours).
- **Single Point of Failure (SPOF) -** Part of a system that, if it fails, will stop the entire system from working. They are undesirable in any system with a goal of high availability or reliability, be it a business practice, software application, or other industrial system.
- **Stock Keeping Unit (SKU) –** An organisation assigned product identification code that uniquely identifies a product or bundle of products that helps the item to be tracked for inventory and commercial events.
- **Structured Query Language (SQL) -** Special-purpose programming language designed for managing data held in a relational database management system (RDBMS), or for stream processing in a relational data stream management system (RDSMS).
- **Supply chain** - Chain of individuals and organisations involved in getting a product or service from the producer to the consumer.
- **Supply Chain Management (SCM) -** Streamlining of a business' supply-side activities to maximise customer value and to gain a competitive advantage in the marketplace.
- **Tamper Proof/Physical Security Feature** - Features, including techniques to provide tamper evidence and elements to prevent transfer and reuse.

- **Traceability** - Ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component.

- **Tracing** - Ability to identify the past or current location of an item. Where an item is intercepted, tracing allows the verification of the products route back to its origin and allows the retrieval of a specific product's time and location history.

- **Tracking** - Concept of marking products with a unique identifier so they can be monitored from the point of production up to the point of sale to the customer, including each step of the process, creating a time and location history for every step.

- **Unique Device Identification (UDI) System** - Intended to assign a unique identifier to medical devices within the United States. It was signed into law on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007.

- **Unique Identifier -** Identifier which is guaranteed to be unique among all identifiers used for those objects and for a specific purpose.

- **Unit Packet** - Smallest individual packaging of a tobacco or related product that is placed on the market.

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PART II PRACTICAL CONSIDERATIONS FOR IMPLEMENTING A TRACK AND TRACE SOLUTION (TO BE COMPLETED TBD)

Part one of this multi-part guide focused on the core concepts and technologies related to track and trace under the auspices of the Protocol. Part II focuses on providing practical guidance on how to go about implementing a solution

8   CHOOSING AND IMPLEMENTING TRACK AND TRACE SOLUTIONS

The core objective of the Protocol is to eliminate illicit trade in tobacco products. Art. 8 which is the focus of this guide, is intended to secure the supply chain and to assist in the investigation of illicit tobacco trade. Article 8 describes in general terms what is required from parties to be able to monitor and control the production and import of tobacco products by implementing a track and trace solution. The following section will look at the practical aspects of what is required and how to go about fulfilling the requirements in a structured way.

There are 4 key steps in the journey:

Step 1: entails planning and analysis of the existing environment to identify gaps and potential strengths and highlight the specific requirements for a track and trace program to be delivered and outline the plan for delivery.
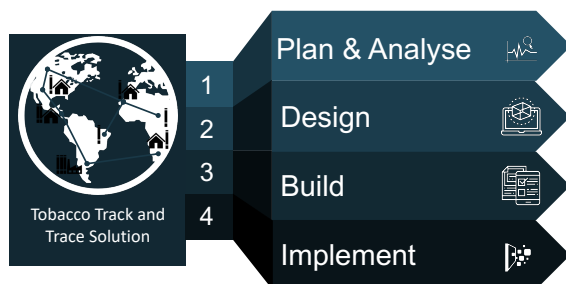
Step 2: Once the environment is understood and the governance model is established the program can proceed to designing, which will include the concurrent establishment of a project delivery team, developing a motivated and defensible business case and the solution blueprint.

Step 3: is the building of the solution which could entail procurement and selecting solution providers as well as upgrading of enterprise systems to interface with the T&T solution.

Step 4: Delivering the solution.

Delivering and implementing a track and trace solution is not merely a procurement exercise, it is a journey with many steps requiring a structured, coordinated approach to ensure successful delivery on the requirements of the Protocol.

8.1   STEP 1: PLAN AND ANALYSE

There are 3 key areas that need to be analysed thoroughly before a Party chooses a track and trace solution.

A. **Governance:** A governance model develops structures, roles and relevant responsibilities based on the Protocol requirements and problem statement.

Figure 16: Solution Considerations

B. **Illicit trade:** The challenges of illicit trade are not homogenous across all countries. Governments need to consider the size and nature of illicit trade as well as the specific fraud types that they are faced with, and whether the country is largely a source, transit or destination country from an illicit cigarette perspective.

C. **Customs and Excise:** The customs and excise environment is the base of control for any track and trace solution. It is critical that a thorough understanding of this area is obtained so that the gap between what exists and what needs to be implemented can be fully understood and appreciated.

These considerations are explored further in the section below.

a) *Assessment of the Size and Nature of Illicit Trade*

Understanding the size and nature of illicit trade locally is important because different manifestations of illicit trade require different policy and operational responses. There is no generic solution to combat illicit trade. This is mainly due to the diversity of the size and nature of the illicit trade facing each country, the stakeholder and supply chain landscapes, the capabilities of the government agencies to mitigate the risks, and the robustness of the legislation to enable effective administration and enforcement.

SAMPLE ESTIMATE OF # ILLICIT STICKS IN A COUNTRY		
1. CALCULATE TOTAL CIGARETTE CONSUMPTION		2. CALCULATE NUMBER OF CIGARETTES ON THE MARKET LEGALLY
Population	1,000,000	Legal cigarette market (based on declared volumes from licensed manufacturers & importers – cigarettes exported))	400 million cigarettes manufactured locally + 200 million cigarettes imported legally – 100 million cigarettes exported legally =
% of population that smokes	20% = 200,000 smokers		
Each smoker smokes # cigarettes per day → #x365	10 a day → 3,000 a year		
Total cigarettes smoked in the country = # of smokers x #of cigarettes smoked per year per person	200,000 smokers x 3,000 cigarettes = 600 million cigarettes smoked in the country a year		
= 600 million cigarettes smoked in the country		–	=500 million legal cigarettes in the country
ILLICIT CIGARETTES = 600 million smoked – 500 million in the country legally = 100 million illicit sticks = 17% OF THE MARKET			

Figure 17 Example of calculation of the size and prevalence of illicit trade

With this in mind, assessing the size and prevalence of illicit trade is important from two perspectives: it allows government to develop a business case to prioritise and fund activities aimed at curbing illicit trade, and it allows for the tracking of trends over time to assess the impact strategies are having.

It is important to understand that the tobacco industry has an interest in inflating the size and prevalence of illicit trade, and indeed are known to do so. Consequently, estimates are preferred if they have been done by independent, reputable academics who use a transparent estimation methodology (which ideally triangulates the outcomes of more than one calculation) and whose work has been peer reviewed.

Assessing the size and prevalence of illicit trade is a relatively specialised field, and Parties may benefit from securing the services of independent institutions who have refined a range of methodologies[22], and whose work is peer reviewed (e.g. the FCTC Knowledge Hub on illicit trade based at the University

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[22] Hana Ross. Understanding and measuring tax avoidance and evasion: A methodological guide. Washington DC 2015. DOI: 10.13140/RG.2.1.3420.0486
http://www.tobaccoecon.uct.ac.za/sites/default/files/image_tool/images/405/Publications/reports/Understanding-and-measuring-tax-avoidance-and-evasion-A-methodological-guide1.pdf;

of Cape Town's Economics of Tobacco Control Project). Parties could also supplement these assessments with their own internal analyses which could include a high-level estimation of their own, using verified methodologies.[23]

At its very simplest, this could be a calculation along the lines of figure 18. While this model would not necessarily be as sophisticated as the models developed by academics or economists, it could provide sufficient insight if correctly executed to serve as a basis for an illicit trade strategy. Once such model is developed and understood, it can be conducted by Parties themselves and repeated after a period of time, to assess the impact the Party has had on illicit trade.

Sources of illicit trade

Perhaps one of the most critical aspects in better managing illicit trade lies in understanding the sources of illicit cigarettes in a country. Typically, this would include one of four key sources, each of which requires a different legislative, operational and systems-based response:

Illicit cigarettes that are manufactured locally by licensed legitimate manufacturers are probably best managed through production controls and tax stamps; while those manufactured by unlicensed illegal manufacturers require a strong intelligence framework. Illicit cigarettes coming from free trade zones require political will to introduce the same regulatory frameworks that would apply outside of free trade zones. Clamping down on illicit cigarettes from countries that do not regulate the production of illicit whites may require conversations around designating these countries as tax havens.

Questions you should be asking

Size and prevalence of illicit trade
- Can you quantify the size and prevalence of illicit trade in your country?
- Is information independent from the tobacco industry available?
- Is the methodology used transparent and are results peer-reviewed?

Manifestation of illicit trade
- Is the country predominantly a manufacturing, transit or destination market?
- Do illicit cigarettes predominantly come from local manufacturers, or are they smuggled across the border?
- Are cigarettes produced legally but later diverted to illicit channels, or were they made in unlicensed facilities?
- Were illicit cigarettes manufactured in free trade zones or in countries that do not actively criminalise the production of illicit whites?
- Are smuggled cigarettes predominantly branded packs, counterfeits, or illicit whites? How do they enter your country?
- Which outlets sell illicit cigarettes?
- Are illicit cigarettes mostly sold as packs, or as single sticks? Is the illicit cigarette trade connected to large scale criminal operations such as tobacco tax evasion, transfer pricing and money laundering?

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[23] Hana Ross. Understanding and measuring tax avoidance and evasion: A methodological guide. Washington DC 2015. DOI: 10.13140/RG.2.1.3420.0486
http://www.tobaccoecon.uct.ac.za/sites/default/files/image_tool/images/405/Publications/reports/Understanding-and-measuring-tax-avoidance-and-evasion-A-methodological-guide1.pdf;

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b) Conducting a Diagnostic Assessment of the Customs and Excise Environment

The primary objective of the Protocol is to eliminate illicit trade, and this can be best achieved through a whole-of-government approach, involving health, customs and revenue, law enforcement, the criminal justice system and the legislature. However, the administering agency would usually be the customs and excise and/or revenue agency as they are most likely already involved with effecting the operational, licensing, compliance management and enforcement requirements of the Protocol.

Illicit trade and excise revenue leakage are complex, multi-faceted problems. There are no simple, "one size fits all" solutions, and a track and trace solution is not a panacea that will address all illicit trade issues. Instead, what is required is a concerted effort involving human resources, business processes and technologies, addressing multiple business areas and fraud typologies, which can be sustained over time.

1 **Stakeholder Registry**
Who are, and what is the compliance level of registrants?

2 **Risk Management**
How able is the agency to identify risky manufacturers and importers?

3 **Audit and Enforcement**
Does the agency have the required capacity and capability to mitigate identified risks?

4 **Business Systems and Technology**
Are the agency's systems and technological infrastructure fit for purpose?

5 **Organisational Strategy and Management**
Will the organisational strategy and key performance indicators (KPI's) enable the track and trace solution?

Figure 18: Diagnostic Assessment

A diagnostic exercise from an excise management perspective typically includes an assessment of 5 capabilities within an organisation as displayed in figure 18, allowing the agency to assess which strengths it can leverage, and which weaknesses or gaps its design and solution would need to compensate for (for example, if it has very limited enforcement capacity or no business intelligence capabilities, this would influence the design and support

required from the solution provider.)

The outcomes of the diagnostic would provide a baseline to inform the development and implementation of the track and trace solution.

Review the Stakeholder Landscape

A critical aspect of any track and trace solution is the stakeholder landscape within which it is to be implemented. There are a number of stakeholders who have an interest in ensuring the track and trace solution succeeds, and as

Health Perspective
Reduce Consumption
Implementing policies to reduce consumption of tobacco products

Trade Perspective
Facilitate legitimate trade
Providing a framework that encourages and enables trade

Fiscal Perspective
Collect Revenue Due
Collecting all revenues due to the fiscus

Enforcement Perspective
Prosecute Non-Compliance
Ensuring compliance with the

Figure 19: Government Drivers for Track and Trace

many in the tobacco supply chain who would prefer it never gets implemented. There are a number of competing factors that would drive a Party's need for a track and trace solution as displayed in **Error! Reference source not found.**19.

Government has a multi-faceted role and responsibility in ensuring that these drivers are balanced and prioritised. The key to achieving this is to establish a stakeholder management strategy and plan
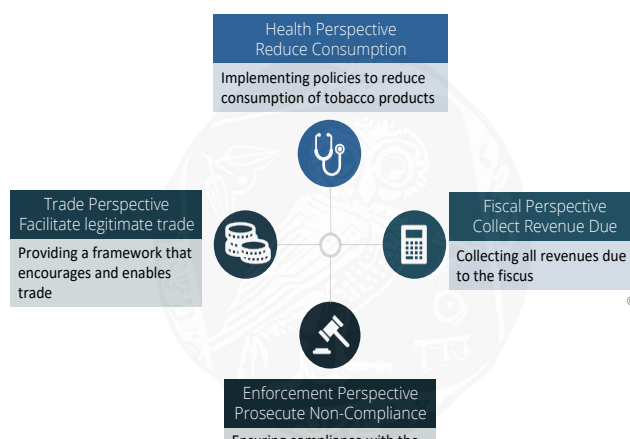
which will ensure effective engagement and interaction with stakeholders throughout the lifecycle of the solution.

When commencing the stakeholder engagement strategy, it is useful to create a 'map' of stakeholders combining aspects from the questions above but taking into consideration the history and proven tactics of the tobacco industry to thwart any government-driven tobacco regulation[24]. The track and trace solution will have to be implemented for an industry that has opposed independent traceability while accusing governments of not taking action against illicit trade; whose budgets are greater than many countries' GDP's; which makes up one of the most influential political lobby groups in the world; and which has itself been associated with illicit trade.

Traceability Stakeholder Roles and Activities

A number of roles are fulfilled by the different stakeholders as detailed in **Error! Reference source not found.** below[25]. Some of the stakeholders may be responsible or accountable for specific deliverables or functions (for instance the customs agency taking the overall lead), while it may be necessary to consult others (for instance, to establish the number of production lines being run by tobacco manufacturers), and some who simply need to be informed them of policy decisions that government has taken.

The tobacco industry is a stakeholder in the sense that whatever regulation and system is ultimately chosen has to be implemented by them, and their input may be required in respect of the local manufacturing realities. However, international experience highlights the importance of government independence in developing policy positions, and of the very real risk of regulatory capture where government adopts policy positions and systems that simply reflect preferred industry positions and do little in real terms to reduce the potential risk of packs being diverted to the illicit market. For this reason, engagements with the tobacco industry should be limited only to issues where it is absolutely necessary, and government should develop and adopt policy positions entirely independently from industry (see for instance Art. 5.3.)

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[24] http://www.bath.ac.uk/health/research/tobacco-control/
[25] For an alternate view see Annex 5: Stakeholder Roles/Activities In The Supply Chain

STAKEHOLDER	ROLE/ACTIVITY	©
UNIQUE IDENTIFIER PROVIDER	Creation and distribution of unique identifier (UID) for serialised marking	
SECURITY FEATURE PROVIDER	Produce, store and securely convey security features to authorised entities	
MANUFACTURER	Serialisation: Implement serialisation solution on production line Authentication: Authenticate (validate) products prior to sale	
DISTRIBUTOR	Scan and Upload: Scan UID's and upload supply chain event data	
TRANSPORTER	Scan and Upload: Scan UID's and upload supply chain event data	
RETAILER	Scan and Upload: Scan UID's and upload supply chain event data	
CONSUMER	Authentication: Authenticate products	
GOVERNMENT	Authentication: Authenticate products for enforcement Reporting: Authenticate products for enforcement Sharing: Information sharing locally, regionally and globally	
DATA MANAGEMENT PROVIDERS	Data Management: Create secure, centralised store for all traceability data with back-up and redundancies	

Figure 20: Stakeholder Roles and Activities

(See the later section on an appropriate engagement model with the tobacco industry.)

Understand the Supply Chain Process

The tobacco supply chain is very broad, commencing with tobacco growers and other raw material providers (acetate tow for filters, cigarette paper, etc.) to manufacturers, wholesalers and distributors, through to retailers and finally consumers. In terms of the scope of coverage of the traceability solution, Art 8. of the Protocol requires the following:

Section	Protocol Text
7	A tracking and tracing system controlled by the Party for all tobacco products that are manufactured in or imported onto its territory
10	Each Party shall require the further development and expansion of the scope of the applicable tracking and tracing system up to the point that all duties, relevant taxes, and where appropriate, other obligations have been discharged at the point of manufacture, import or release from customs or excise control

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The first requirement is relatively straight-forward and can be understood to mean that all tobacco products meant to be consumed in any country (whether locally produced or imported) must comply with the requirements of the track and trace solution. The scope of this requirement extends to the production process for manufacturers and the border control process for importers.

The second requirement, however, is not as straight-forward. Typically, the point of taxation (excise and VAT) for manufactured products occurs at the point of production (duty at source) or at the point of sale to the first non-related entity. For imports and exports, the customs control commences and concludes when the goods cross the border which is usually the point where import duties become due. However, the nature of excise laws and control regimes around the world vary in terms of the points of taxation and where customs and excise control begins and ends.

Consequently, the scope for this requirement depends on where an individual country has put the point of taxation.

As per Art.8.10 of the Protocol, a tobacco traceability solution will need to consider product movements into, within and out of the country:
- **Internal Market:** the tracking and tracing of tobacco products produced within the country and intended for local consumption;
- **Imports:** The marking of tobacco products manufactured outside the country, prior to the goods being made available for local consumption (packs can be marked at the time of manufacture in the foreign country, or marked at the time of import);
- **Exports:** The application of unique identifiers for traceability purposes for goods manufactured locally, where those tobacco products are intended for a foreign market outside of the country (including cigarettes intended for sale in duty free shops); and
- **International Transit:** The Protocol stipulates that free trade zones and transit shipments should be subject to the same controls as other tobacco products under the Protocol and prohibits the intermingling of tobacco products with other goods in the same container.

Understanding the end-to-end supply chain process, in terms of stakeholders, supply chain events, data generation, maintaining integrity as well as storage points and accessibility is critical to ensuring a practical and efficient track and trace solution.

Considering the requirements of the Protocol itself, what we know about global illicit trade in general and the tobacco industry's history in relation to illicit trade, the following design principles should be considered as part of developing an in-depth understanding of the customs and excise environment:

- **Independent of industry** – at all levels and to the greatest extent possible;
- **Secure** - impervious to manipulation, circumvention, or fraud;
- **Bespoke** - catering to the local context and specific country dynamics;
- **Scalable** - in order to expand the solution to multiple sites and potentially to other product categories e.g., alcohol, pharmaceuticals, beverages, etc.;
- **Practical** - taking into consideration the realities of tobacco manufacturing and related supply chains (this includes best efforts to be minimally evasive to industry);

- **Collaborative** - amongst key stakeholders and system users as well as with the Global Information Share Point[26];
- **Integrated** - with key illicit trade enforcement resources, policies and operations;
- **Flexible -** so they can easily be adapted to the changing illicit trade modus operandi and as new solutions and technologies become available.

Questions you should be asking

Implementation
- What problems need to be addressed and how can they be quantified?
- What policies and processes need to be addressed and improved?
- Do existing systems need to be replaced/upgraded?
- Does the current business structure support the desired outcomes?
- How will the outcomes be measured?

Engagement with stakeholders
- Who are the stakeholders? Who has an interest in the track and trace solution or may be affected by it?
- What are their interests? Will they benefit from it or does this impose additional obligations or burdens on them?
- Who is likely to support or oppose it?
- How will they be affected? Will their business processes change, will business costs increase, etc?
- What is their level of influence?

Customs oversight to date
- Which entities in the tobacco supply chain are currently subject to customs oversight, and which ones should be?
- What level of detail (data) will be required to fulfil the oversight and enforcement obligations?

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a) *Define the governance model*

Developing a governance model begins by understanding the Protocol requirements and defining a problem. There is a very strong correlation between a governance model and the problem statement as the latter is a crucial determining factor in selecting an appropriate model and related attributes. Typically, governance models contain three key components:

Oversight - which establishes key roles and responsibilities, policies and procedures;
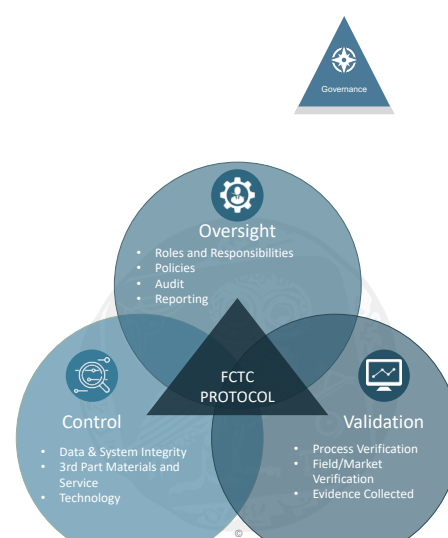
Figure 21: Track and Trace Governance Model

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[26] Focal point of all track and trace information gathered from solutions around the world as specified in Art.8.1

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Control - which, in the case of the Protocol's requirements relies on various technologies (security features, data capture etc.); and,

Validation - that ensures that the overall system is checked, and that integrity is maintained over time.

Figure 21 depicts a governance model for track and trace based on generally accepted good practice combined with key solution elements that would be required for effective implementation of the Protocol.

Practically, most competent authorities will most likely not build the system themselves but would instead rely on outside vendors and suppliers. Nevertheless, through the governance model the competent authority can still ensure that obligations and requirements are met by leveraging the technologies and controls built into the system (e.g., reports, alerts etc.) and by also conducting periodic checks (audits) both on the system itself and within the supply chain. For example, competent authorities and government enforcement resources should regularly conduct periodic site visits to manufacturing facilities, warehouses and distribution points as well as checks on packs and cartons in the retail market.

Developing the right governance model for track and trace

Policy options need to consider the tasks and activities that need to be undertaken as well as who will perform them. The tobacco industry must not be responsible for directly implementing any of the critical obligations and tasks within the solution. As per Article 8.12 of the Protocol, *"key solution obligations assigned to the Party shall not be **performed** by or **delegated** to the tobacco industry."* This is reiterated throughout this guide because the industry has gone to great lengths to position itself and/or its proxies as potential candidates to implement solutions.

The governance model must clearly assign key requirements to various stakeholders across the solution. For this it is useful to assign specific accountabilities for persons who are individually ***responsible, accountable, consulted and informed*** *for different aspects of the implementation*:
- **Responsible:** Who should perform an activity or do the work;
- **Accountable:** Who is ultimately accountable and has Yes/No/Veto;
- **Consulted:** Who needs to provide feedback and contribute to the activity; and,
- **Informed:** Who needs to know of the decision or action.

b) Solution Consideration Checklist

	CRITICAL SUCCESS FACTORS	✓
	Governance Model	
	Governance model clearly sets out who is accountable, responsible, consulted and informed for all key solution obligations, activities and tasks.	☐
	Tobacco industry performance of key requirements is kept to a minimum.	☐

Size and Nature of Illicit Trade	
Source of illicit trade estimates is independent from tobacco industry.	☐
The different faces of illicit trade, and the relative size of each, are well understood.	☐
A framework has been developed against which to assess the impact strategies are having on illicit tobacco.	☐
Regular reviews are conducted of the manifestations of illicit trade and changes in trends and patterns.	☐
Diagnostic Assessment of the Customs and Excise Environment	
We have a baseline of current performance levels.	☐
We have conducted a gap analysis of protocol requirements versus current capability.	☐
We have a map of stakeholders involved in tobacco supply chain, and a formal stakeholder engagement strategy.	☐
The regulatory framework gives customs and excise sufficient control over all supply chain events and actors.	☐
The new system has been designed with integration and interoperability with our other systems in mind.	☐

8.2   STEP 2: DESIGN

A legislative gap analysis is required to quantify what powers and authorities the Party *has*, compared to what it *needs*.

Article 8 is simply one of a number of obligations that arise from the Protocol – all of which should be read together in a broader context that seeks to deliver on the main objective of the Protocol: seeking to prevent tobacco from entering the illicit supply chain. (While the guidelines in the Protocol are sometimes referred to as simply "principles and recommendations to assist Parties in best practice implementation of their treaty obligations," under the Vienna Convention on the Law of Treaties and customary international norms, the guidelines are in fact binding on Parties.[27])

FCTC Protocol Article 8 [28]

Compulsory provisions – Parties _must_ introduce the following in such a way as to give effect to the spirit of the Protocol:

- Article 8(2): Each Party shall 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 onto its territory considering their own national or regional specific needs and available best practice.
- Article 8(3): Each Party shall require that unique, secure and non-removable 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 and tobacco products
- Article 8 (13) Each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, _interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary_.

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[27] See e.g. on the legal effect of FCTC guidelines, https://pdfs.semanticscholar.org/bd13/9ca79344d1e946a28a44ec79e27817b5a569.pdf

[28] For complete text see the relevant Protocol sections in Annex 3&4

The Protocol establishes a number of obligations and requirements for Parties to which national law has to be aligned. Parties may need to either amend their existing legislation or promulgate new legislation. Some provisions of the Protocol can likely be implemented under existing legislation whilst other provisions may require considerable changes to regulations or legislation. For example, most countries already require that manufacturers and traders of excisable goods (including tobacco) be licensed. Similarly, in many countries tobacco products are already subject to fiscal marking regimes (tax stamps), which are similar to several of the track and trace requirements as set out in Article 8 of the Protocol. In these instances, Parties can simply phase in additional Protocol requirements as the regulatory authority is established under law.
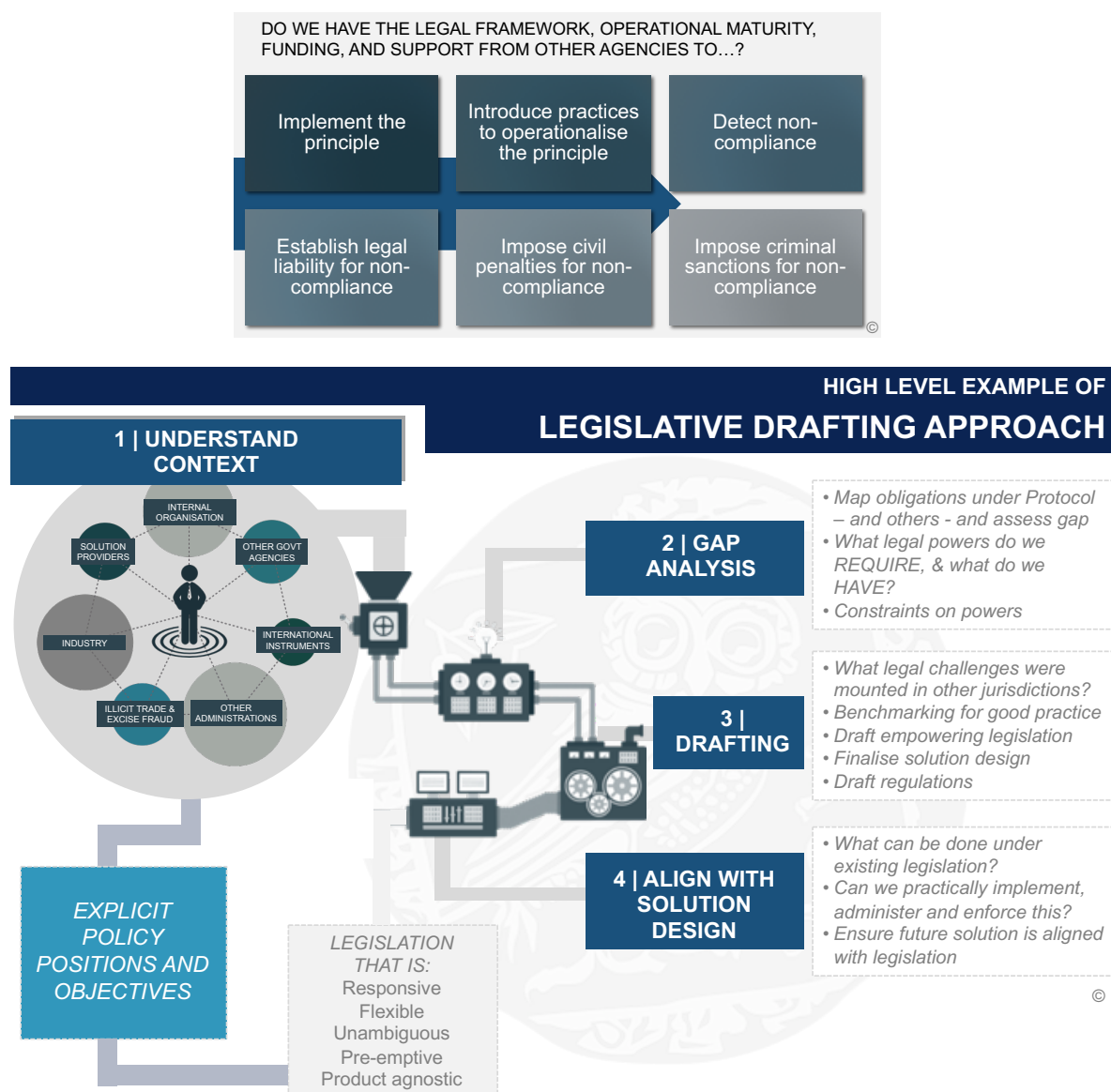
Figure 22: Basic Obligations Referenced in Legal Framework

From a legislative perspective Parties need to verify the extent to which their existing legal framework lets them meet the basic obligations introducing legislation to entrench the principles themselves; and introducing operational solutions and practices to operationalise the principles. These should allow a Party to detect non-compliance, through a range of activities from inspections and audits, to using

special investigative techniques, and more advanced solutions like taggants and markers; to establish legal liability for non-compliance, to ensure that actors across the supply chain can be held legally liable; and to impose civil and criminal penalties for non-compliance.

In drafting legislation, a Party faces a number of key design considerations:

1. Understanding the context: Good legislative design is very much dependent on an in-depth understanding of the environment in which an agency operates, which includes a comprehensive understanding of, for example:
   ▪ The Party's internal organisation, including its current legislative powers, the policy choices at its disposal, and its operational capabilities and maturity;
   ▪ How illicit trade manifests itself, and what legal gaps and loopholes contribute to illicit trade;
   ▪ Other government agencies and the extent to which they may have a role to play in terms of operationalising or regulating the provisions of the Protocol;
   ▪ Other administrations to identify good practices, and to ensure alignment and interoperability where appropriate;
   ▪ Industry's tactics and practices, supply chain security solutions the industry may have adopted, and anticipating legal challenges; and
   ▪ Solution providers, to understand what potential technologies could assist in meeting the Party's obligations under the Protocol.
2. This allows the Party to develop a legislative gap analysis, which would include mapping the Party's obligations under the Protocol, and assessing what legal powers it *has*, and what legal powers it *requires*. To what extent are the requirements already incorporated into legislation, are reflected in operational policies, and are actually implemented operationally? If they have been implemented to what extent is the implementation ineffective or inefficient (due to, for instance, limited capacity, systems constraints, insufficient intelligence etc.);
3. The drafting process is underpinned by an understanding of good practice in other jurisdictions and pre-empting potential legal challenges from the industry. Parties may benefit from phasing the drafting of legislation by preparing primary, empowering legislation as soon as it has adopted explicit policy positions and principles, then refining the solution design, which is used, in a second phase, for the drafting of regulations or subsidiary legislation to operationalise the principles;
4. Ensure alignment with the envisaged solution design: In order to secure alignment between the ultimate solution design and the policy position and principles Parties seek to introduce, Parties may find it useful to include a legal representative in the project team from the start.

Both the solution design process and legislative processes rely on very similar inputs. As a result, many agencies find it beneficial to run both of these processes concurrently.
This is particularly important because legislation often takes months or even years to promulgate. While secondary legislation can typically only be drafted once a solution design blueprint has been developed, primary legislation can easily be drafted once an agency has adopted a policy position.

Questions you should be asking

Starting the Legislative Process
▪ What type of illicit trade are we trying to address?

- Which of the obligations under the Protocol applies to our agency?
- What kind of legislative tools exist already?
- Which actors and supply chain events can we currently control, and which ones do we need to control to better secure the supply chain?

Coordination with other Agencies

- Who is responsible for the obligations that do not apply to our agency?
- Which other agencies or departments may have a parallel interest or obligation with whom we need to coordinate our regulatory response?
- What legal powers do other agencies have that could be leveraged without having to change existing legislation?
- Are their external legislation influences that may limit our room to act (e.g. on the use of electronic data in litigation)?

Potential Tobacco Industry Interference

- What legal challenges have the industry mounted against similar legislation elsewhere?

Legislation Checklist

CRITICAL SUCCESS FACTORS	In Principle	In Practice
▪ Understand the obligations under the Protocol.	☐	☐
▪ Obligations under the Protocol are (or will be) reflected in legislation.	☐	☐
▪ Obligations under the Protocol are (or will be) reflected in operational instructions or regulations.	☐	☐
▪ Legislation and operational practices are aligned.	☐	☐
▪ Sufficient capacity to develop, implement, administer and enforce the legislation.	☐	☐
▪ Effective date of new legislation is aligned with planned operational go-live date.	☐	☐
▪ Legislation is aligned with other legislation (on e.g. tax stamps on packs vis-a-vis placement of health warnings on packs.)	☐	☐
▪ Primary / empowering legislation is sufficiently flexible to cater for changes in modus operandi in illicit trade	☐	☐

8.3 STEP 3: BUILD

The Protocol provides little guidance on how track and trace systems should be developed and paid for, only that costs must be borne by the tobacco industry. There is no one size fits all model when it

comes to solution development however, Parties essentially have two choices, build the solution themselves (or a portion of the solution e.g., UID generation) or procure a solution from the private sector. When it comes to pricing there are also no universal guidelines as many variables can affect the overall price. When attempting to determine the cost of a solution a number of variables need to be considered as the size and breadth of the solution will depend on the particular dynamics of the country and overall industry footprint and their respective supply chain(s). The number of production lines, the number of physical locations where the solution will be rolled out, the volume of products to be tracked and trace and the specific technical specifications. Consequently, the cost will depend on these and other factors. Some of the most critical considerations, however, involve the overall robustness and security within the solution.

Parties may face a number of critical challenges in selecting vendors, all of which require careful management: if the volume of tobacco products is too low, it may not be commercially viable for a solution provider to tender, which may require a broader tender to be issued that also includes other excisable products; Parties may be tempted to implement low-cost solutions only to find that the secure marks are of poor quality and do nothing to actually secure the supply chain; solution providers may pitch extremely sophisticated solutions that the country does not have the capacity to implement, administer or enforce; or solutions developed by or associated with the tobacco industry may be presented through proxy organisations to obscure their true genesis. Another consideration is one of "vendor lock" whereby a solution vendor provides a solution that is so specific, the Party may not be able to swap it out for another solution should it the original not be performing adequately. Parties should consider how best to ensure they build in contractual performance measures and implement solutions that can be replaced if required.

There are credible, real-world reference points where highly secure track and trace can be achieved for only pennies (USD) per pack or even less. Although the tobacco industry will most likely oppose any costs added to their products, the reality is that adding track and trace to the cost of tobacco products is miniscule compared to the recommended tax rates and industry profit margins. Parties should not be fooled by industry lobbying that adding track and trace to their products will result in job losses or factory closures. In fact, evidence suggests that most job losses in the industry are attributable to automation and improved efficiencies in the tobacco industry – not to any regulatory efforts on the part of governments. Evidence similarly suggests that much of the price increases in tobacco products are attributed to tax rate increases but are in fact attributable to industry price increases. Concerns about cost should not prevent a Party from implementing a solution: the miniscule cost that secure marks would add to the price of a pack of cigarettes pale in significance considering the retail prices of packs.

In terms of procurement, the Protocol does not stipulate how the solution should be built or procured, only that it must be independent of industry. For most competent authorities, the technology and operation of a track and trace system will go well beyond their core competence and the technologies (security features, high speed printing, supply chain event monitoring) and business processes associated with track and trace will most likely not be familiar. As a result, these functions will likely be outsourced. How this is done will largely be determined by the Party's procurement laws. Most current systems in operation have been based on one of two models:

1. **Straight Procurement** - where the Party undertakes a procurement process (tender) and contracts with a third-party service provider for a set duration of time and for an agreed price; or
2. **Public Private Partnership** - where the Party and a third-party establish a business entity together to provide the track and trace functions.

A) KEY CONSIDERATIONS

There is no procurement or cost model that applies universally for all countries. In terms of cost, there are many common elements across most track and trace systems. There are four main factors that contribute most to the overall solution cost: (1) dynamics of tobacco supply chains; (2) solution scope; (3) breadth of supply chain event monitoring; and (4) overall solution security and robustness.

Dynamics of Tobacco Supply Chains

One of the most significant elements of cost relates to the nature and make-up of tobacco supply chains. Is there local production, are there imports, exports, transits? What is the point of taxation e.g., are duties paid on production or later in the supply chain? How many production facilities are there in the country? How many units are produced? How many ports of entry are there? The more complex the environment, the more sophisticated the solution design needs to be, and the more costly it is likely to become.

Solution Scope and Coverage

Although the Protocol only refers to the tracking and tracing of tobacco products, many regulatory authorities also expand their systems to cover other goods with similar attributes. For example, since other excisable goods like alcoholic beverages are also subject to illicit trade, some countries also implement similar solutions across other excisable goods. In this case certain solution costs (notably capital expenditure) can be shared across various industries.

Breadth of Supply Chain Event Monitoring

Will the Competent Authority conduct inspections along the supply chain and where will they conduct them e.g., warehouse, retail? As a general rule the number of units involved will also have a significant impact on cost, with high-volume production or import typically costing less per unit than low volume markets. Another major consideration relates to the "breadth" of the supply chain event monitoring (see section 3.6). The Protocol stipulates that track and trace must be carried out up until such time that all duties and taxes have been paid. This would vary from country to country depending on the customs and excise law. Recording of the supply chain events along the supply chain requires both the use of aggregation at various levels (pack to carton, carton to master case etc.) as well as requiring that scanners be used along the supply chain. Again, parties should not be fooled by typical industry rhetoric that this will add onerous costs. Tobacco companies (and most other companies) are recording the events along their supply chains in any event so they know exactly where their goods are headed. In today's modern supply chain environment, no one simply loads a container or truck and then simply forgets it. Supply chain tracking is a business reality that has been around for many years. It relies on the use of low cost, off-the-shelf scanners and accepted industry standards like bar codes and data matrices and is not unduly onerous on any business.

Overall Solution Security and Robustness

This is perhaps the most critical component of the solution in terms of efficacy but is also a key determinant of the cost. The type and number of security features used in the solution is important as it relates to the robustness but is directly proportional in terms costs. The bigger the illicit trade threat and the higher the likelihood of fraud in a market, the more sophisticated the features will likely need to be. Sophisticated features that are less susceptible to fraud cost more. Parties will need to consider their specific risk types and propensity to determine the balance between securing the solution and making it cost effective.

Additionally, the means and mechanisms used by government to ensure the system has not been compromised can contribute to the overall costs, as can inspection activities at various points in the supply chain. Authentication devices in the retail or distribution environment can be used as a robust check on the overall system to ensure compliance, but will require the development of specific purpose-built devices or applications that can authenticate the various security features (e.g., covert features) and ensure that tobacco products are where they are supposed to be (e.g., intended destination market). The number of devices required/sophistication of the application will impact the overall solution cost. All of this should be clearly set out in the solution specification and cost benefit analysis.

B) ELEMENTS OF COST

A track and trace system will include both capital expenditures (CAPEX) and ongoing operating expenditures (OPEX) which are typically made up of hardware, software, data storage fees, consumable materials (e.g., ink, fiscal marks/tax stamps etc.) and labour. Some of the equipment typically used is highly specialised and, in some cases, will require customisation in order to meet the requirements of the production environment. For example, some of the high-speed validation system components cost about as much as a luxury car. The figure below depicts the typical cost elements. It must be noted that the pricing for these cannot be readily compared on a universal basis as each country's implementation will depend on a range of factors as discussed above. The table below provides an overview of the primary cost elements and their overall role in terms of track and trace.

COST ELEMENT		ROLE IN TRACKING AND TRACING
	Secure Mark	Direct marking (ink) or an affixed marking (e.g., tax stamp)
	Printers	Used to print unique IDs
	Label applicators	For affixed marks (given the prevalence of tax stamps in the tobacco regulatory environment, these are often standard/factory installed on tobacco manufacturing machines)
	Validation Systems/ High speed cameras	To capture and provide quality assurance of unique IDs
	Scanners	Used to capture supply chain events

	Query Tools	The development and maintenance of software applications that allow competent authorities to manage the track and trace data, conduct queries and analyses, and monitor tobacco supply chains.
	Data Storage	Of unique IDs and corresponding supply chain events
	Consumables	Labels, inks etc. (e.g., for aggregation bar codes)
	Labour	For build, maintenance and ongoing support of the system
	Authentication Devices	Purpose built devices or applications (apps) that allows enforcement and potentially other actors to authenticate products as genuine.

Table 8: Traceability Solution Cost Elements

Costing of a solution is simply not possible without first having a detailed solution specification that sets out clearly all of the solution components, key activities and overall implementation model. This cannot be done without first conducting an environmental scan, mapping of tobacco supply chains and preparing an overall strategy. Roles, responsibilities and activities of key supply chain actors will also need to be clearly set out and form part of the overall detailed solution specification.

Costing Checklist

CRITICAL SUCCESS FACTORS	✓
A volumetric analysis has been conducted in terms of overall production, import and export volumes.	☐
The solution design is complete, and scope agreed upon.	☐
Appropriate types and levels of security have been considered.	☐
All cost elements have been fully considered for the defined solution design.	☐
Clearly defined specifications have been developed to facilitate an 'apples-to-apples' comparison amongst potential solution vendors.	☐
Consider interface and technical integration costs.	☐
Change management, training and continuous improvement costs should be considered.	☐
Any licensing, support and maintenance costs must be taken into account.	☐
A full solution cost-benefit analysis has been conducted to determine solution break-even point and net present value (NPV).	☐

8.4 STEP 4: IMPLEMENT

Delivering a track and trace solution is not a mere procurement exercise. Governments and competent authorities need to appreciate and understand that it is a journey with many steps, and that a structured, coordinated approach will ensure successful delivery on the requirements of the Protocol. In order to ensure that an adequate solution will be delivered, Parties need to avoid track and trace regimes that are being pushed by the tobacco industry and, in general, restrain their contact with the industry to a minimum. Already existing systems such as tax stamps can play a substantial role and the enforceability of track and trade provision is crucial.

A) THE CASE AGAINST INDUSTRY SOLUTIONS (CODENTIFY/INEXTO)

Questions you should be asking

Industry Interference

- To what extent does this solution have its genesis in the tobacco industry?
- To what extent does the solution provider and/or its key staff have current or historical ties to the tobacco industry?
- To what extent may this solution or earlier versions of it have had an incentive to include business rules that may be biased towards the tobacco industry?
- To what extent could there be concerns about a *perception* of industry control or bias, or about opacity of the system potentially limiting the Party's control in respect of this particular solution?
- If the system has a history of having been developed or used by some of the bigger tobacco companies, to what extent could smaller manufacturers have concerns about the use of the system from an industrial espionage perspective?

Technical Concerns

- To what extent does the solution also constitute a production control measure?
- If the solution relies on digital security features only, how does it compensate for the inherent risk of code recycling, code cloning, and code migration?
- If the solution relies on digital security features only (in other words, an alphanumeric code only, without any other overt, covert or forensic security features), how does it compensate for the very high rate of enforcement field scans that would be required to detect a fraudulent pack[29]?

FCTC Protocol Article 8 [30]

Compulsory provisions – Parties _must_ introduce the following:

- Article 8(2): Each Party shall establish a tracking and tracing system, _controlled by the Party_ for all tobacco products that are manufactured in or imported onto its territory.
- Article 8(3): Each Party shall require that unique, secure and non-removable 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 and tobacco products.
- Article 8(12): Obligations assigned to a Party _shall not be performed by or delegated to the tobacco industry_.
- Article 8 (13) Each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, _interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary_.

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[29] https://tobaccocontrol.bmj.com/content/27/6/706
[30] For complete text see the relevant Protocol sections in Annex

The industry has developed its own marking and track and trace solutions, like Codentify which PMI, BAT, JTI and Imperial use on some of their packs[31].

Track and trace or marking solutions that have their genesis in the tobacco industry, like Codentify and Inexto, face a number of key constraints:

Track and Trace Systems must be Controlled by the Party, and not Performed by or Delegated to the Industry

Codentify as an industry-developed and administered solution fell far short of the independence requirement under the Protocol. Codentify effectively became Inexto when it was sold to Impala (reportedly for 1 Swiss Franc). An internal industry document explains how the transfer was intended to circumvent the independence restriction - by licensing Codentify technology for free to 'credible' third party providers, who in turn "*promote Codentify on their behalf, providing training and support to relevant government officials.*" Codentify might no longer be offered as a solution under that name. With its sale to Impala, the solution was rebranded and is now offered as Inexto. The same solution is reportedly also offered by other third-party service providers under different names.

In selecting suitable track and trace solutions, Parties should pay particular attention to assessing the extent to which potential solutions may have had their genesis within the industry, whether the business rules are sufficiently transparent to ensure that the solution is indeed wholly under the control of the Party, and whether the solution does not in effect give the industry undue control over a system that is meant to regulate it.

Track and Trace Systems Must Use Unique, Secure and Non-Removable Identification Markings

As is evident from information on both the Codentify and Inexto websites, Codentify did not, and Inexto does not appear to use physical security features. It essentially uses simply what is an overt security feature in the form of a barcode, and does not use any of the other overt, covert or forensic security features associated with secure marks. A significant weakness of using digital-only security features is that a code from a legal pack of cigarettes can be readily copied and printed onto multiple illicit packs, without any indication of tampering or copying being evident. Once codes have been copied, the system cannot determine which products with the same code are licit or illicit, and allows for a variety of code counterfeiting opportunities, including code recycling, code cloning, and code migration,[32] allowing genuine codes to be reused multiple times.

As a result, a digital solution like Codentify/Inexto cannot necessarily guarantee that a *product* is authentic, only that the *code* on the product is an authentic code.

Also, digital-only solutions are highly susceptible to code recycling, code cloning, and code migration

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[31] On PMI's website it notes that it tracks around 50% of its cigarettes, presumably using Codentify or its successor Inexto. From the website is not immediately clear why it does not track all of its cigarettes.

[32] Using codes of products rejected in quality control, printing the same code on multiple products, and reprinting codes used in one country elsewhere

– in simple terms, it means that it is easy to literally copy a simple alphanumeric code that is readable with the human eye and print the very same code on other packs. As a result, digital-only solutions, like Codentify and Inexto may have difficulty in meeting the "non-removable" element in Art. 8.3, which incorporates a requirement for marks to be tamper resistant and attack resistant (in other words, impervious to reverse engineering, copying, alteration, side channelling, interception of communication between the security feature and any authentication tool, obsolescence and uncontrolled reuse, simply because there is virtually no practical way to establish if a single alphanumeric code has been applied to more than one pack, and will only be detected if 2 packs with the same code are ever scanned, and in that case, it will impossible to determine which is the legitimate pack from the code alone if there are no secondary physical security features to confirm.

In addition, the system constitutes a highly ineffective enforcement tool, with the cost of detecting illicit packs on the market exceeding the potential revenue losses. Digital marks are incredibly laborious to validate. A study into the effectiveness of a solution that uses digital security only (so, something like Codentify or Inexto-based solutions) as an enforcement tool notes how, "In a relatively small market, a law enforcement authority would have to inspect over 27,000 (almost 31,000) packs per week to have a 90% (95%) certainty that it did not miss a fraudulent pack under the Codentify system. A material-based track and trace solution [in other words one that uses other security features that you can see and feel] would require only 45 (59) pack inspections a week to have the same level of confidence"[33.]

In selecting suitable traceability solutions, Parties should therefore pay particular attention to the extent to which solutions may be more prone to individual codes simply being applied to multiple packs, which is a common concern with digital-only security features not supplemented with material security features.

In terms of assessing whether these – or other – solutions meet the remaining requirements that the markings must be unique and secure, Parties should be mindful of the inherent susceptibility of marks that use digital security features only, from a code recycling, code cloning, and code migration perspective, but also in terms of their efficiency as a field enforcement tool and their ability to effectively and efficiently detect illicit packs on the market.

Industry-associated Solutions Checklist

	CRITICAL SUCCESS FACTORS	✓
	The solution does not have current or historical ties to the tobacco industry.	☐
	The solution provider and its key staff do not have current or historical ties to the tobacco industry.	☐

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[33] Hana Ross, Michael Eads, Michael Yates. Why governments cannot afford Codentify to support their track and trace solutions, Hana Ross, Michael Eads, Michael Yates, https://tobaccocontrol.bmj.com/content/early/2018/02/26/tobaccocontrol-2017-053970

The solution uses a combination of digital security marks (alphanumeric codes) and physical material security features that are more difficult to copy or counterfeit, difficult to remove and are tamper-resistant and tamper-evident.	☐
Is there a clear distinction between the entity that generates/provides the unique identifier, the traceability solution provider and the industry ?	☐
Are digital security marks and physical security features independently (not by industry) verified after placement on each pack?	☐
The solution incorporates a production control measure.	☐

B) APPROPRIATE ENGAGEMENT MODEL WITH INDUSTRY

The Convention and Protocol both contain a number of explicit provisions in respect of engaging with the tobacco industry, across the preamble, article 5 of the Convention, and articles 4 and 8 of the Protocol:

Engagement-related provisions in brief[34]

Compulsory provisions – Parties _must_ introduce the following:

- Preamble to the WHO Framework Convention on Tobacco Control recognised the Parties' "_need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts_".
- Article 5.3 of the Convention: Parties "shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law".
- Article 4(2) of the Protocol: Parties shall ensure the maximum possible transparency with respect to any interactions they may have with the tobacco industry;
- Article 8(12) of the Protocol: Obligations assigned to a Party shall not be performed by or delegated to the tobacco industry;
- Article 8(13) of the Protocol: Interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary.

Practical implications from an engagement perspective

The FCTC was subsequently augmented with a set of guidelines and recommendations aimed at minimising industry interference with tobacco control policies[35.]

FCTC guideline recommendations to minimise tobacco industry interference

- Raise awareness about tobacco industry interference with Parties' tobacco control policies;
- Limit interactions with the tobacco industry and ensure the transparency of those interactions;
- Reject partnerships and non-binding or non-enforceable agreements with the tobacco industry;
- Avoid conflicts of interest for government officials and employees;
- Require that information provided by the tobacco industry be transparent and accurate;
- De-normalise corporate social responsibility activities by the tobacco industry;

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[34] For complete text see http://www.who.int/fctc/protocol/en/
[35] http://www.who.int/fctc/guidelines/article_5_3.pdf

> ▪ Do not give preferential treatment to the tobacco industry.

An engagement strategy should be underpinned by an understanding of the reasons for the restriction on engagement, including understanding how administrative capture works, understanding the tactics the industry uses to influence government policy and operations and key industry arguments in respect of traceability in particular, and with the adoption of a structured approach to engagement.

Informed Engagement

The industry advances a number of arguments which are targeted at securing a policy environment that is more conducive to the tobacco industry.

One of the biggest arguments industry advances is that **illicit trade is the result of high tax rates and tobacco control regulations.** By positioning illicit trade as an unavoidable consequence of high tax rates, the industry seeks to ensure that tax rates are not increased. In order to maximise this argument, industry has a proven tendency to inflate the size and prevalence of illicit trade. In fact, many studies highlight that high tax rates do not necessarily result in more illicit trade[36].

Understanding key industry rhetoric in respect of track and trace and marking solutions

The tobacco industry tends to deploy a number of relatively generic arguments in respect of the development and implementation of a traceability solution, which are frequently not based in fact:

- That they are costly – in fact, tax stamps generally cost mere cents;
- That tax stamps are easy to counterfeit and therefore not effective – in fact, secure and sophisticated tax stamps are virtually impossible to counterfeit;
- That they hamper production speeds – modern, sophisticated marking solutions hardly have any discernible impact on production speeds;
- That their introduction serves little purpose because they target legitimate manufacturers instead of illicit manufacturers – in fact, research suggests as much as 98 percent of all illicit cigarettes come from licensed manufacturers, and big tobacco companies have a long (and recent) history of themselves being involved in or facilitating smuggling;

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[36] Instead, research suggests that a high prevalence of illicit trade is rather attributable to factors like the presence of organised crime and informal distribution networks; the level of corruption; the likelihood of getting caught and the level of penalties; and the extent to which industry itself participates in driving illicit trade and the lack of an appropriate control and enforcement mechanism. Countries like Finland, Ireland, the UK, Sweden and Norway all have high tax rates, but relatively little illicit trade in tobacco products; while countries like Spain, Portugal and Greece have relatively cheap cigarettes but significant illicit trade in cigarettes. See e.g. The Economics of Tobacco and Tobacco Control. National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016

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- That the industry has its own traceability solution – it does, but it was never designed to ensure that packs aren't diverted to the illicit market, uses only alphanumeric codes that are highly susceptible to copying, and in effect has the industry regulating itself;

- That the introduction of additional regulation would make the industry less profitable and would result in plant closures and job losses. In fact, research has for a long time pointed to the majority of job losses being attributed to industry automation and efficiency gains[37]; and

- Offering to partner with Parties in clamping down on illicit trade, instead of the introduction of additional regulation.

STRATEGY & POLICY

- Obtain information about industry volumes, supply chain practices, manufacturing processes
- Independent policy and principles formulation

OPERATIONAL ISSUES

- Push information – e.g. explain new processes
- Operational challenges – e.g. systems downtime, practical compliance issues
- Structured agenda items
- Minuted meetings

All interactions:
- Transparent
- Recorded
- Never with just one staff member
- Not excluding any manufacturers or representative bodies

A Structured Engagement Process

A certain level of engagement with industry *is* necessary. Under the governance model discussed in detail above, for the most part, the tobacco industry would fall into the consulted / informed segment. What is important is that Parties do not substitute their own independent thought processes for policy-positions that favour industry, and that they maintain a professional level of scepticism about the positions advanced by industry or its proxies.

All interactions should be transparent, recorded, never with just one staff member, and should arguably be open for any manufacturers or their representative bodies (to avoid partisan views being advanced by dominant manufacturers.)

Parties should take care to engage with the industry only to the extent strictly necessary but should equally be cognisant of the fact that industry often lobbies and engages using proxies, fronts or intermediaries. As a result, Parties should also take care in engaging with other bodies, agencies, research or individuals, who may be acting as proxies for the industry, or who may otherwise be representing industry interests.

Parties would benefit from retaining the inputs of objective researchers who have not received industry-funding, and whose research has been peer reviewed.

Questions you should be asking

- To what extent does the agency rely on information, evidence or research from the industry, or from bodies or individuals who may have an association with the industry?
- Which individuals or bodies may be acting as proxies for the industry, or with industry funding?

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[37] http://www.who.int/tobacco/communications/events/wntd/2004/tobaccofacts_nations/en/

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> ▪ To what extent has the agency adopted good practice solutions to counter potential abuses of influence by the industry, including requiring all lobbyists to register, stipulating that all interactions with the tobacco industry must be recorded and transparent, and adhering to the FCTC recommendations on minimising tobacco industry interference?

c) SUITABILITY OF EXISTING TAX STAMP SOLUTIONS

More than 140 billion tobacco and alcohol stamps, in the form of securely affixed labels, are issued every year by over 150 provincial and national revenue agencies around the world[38]. Can governments that currently use tax stamps convert their current system to an Art. 8 compliant one?

Tax stamps are not the same as tracking and tracings tools but can be upgraded to accomplish track and trace functions. A tax stamp is a visible tax stamp, label or mark placed on certain types of consumer goods to show that the applicable excise tax has been paid**.** Tracking is monitoring an item through a supply chain, while tracing is the ability to check where an item has been (from ISO 12931 2012). The objective of tax stamps is the proof that taxes are paid. The objective of tracking and tracing is to tell the past, current and future locations of products. Tax stamps are applied on products of the domestic market, but not exported products, unless the exported market requests tax stamps. Sophisticated tax stamps have a trace characteristic (telling where the cigarettes come from), but in most cases not a tracking characteristic (there is no aggregation between packs, cartoons and master cases and there is no tracking of the product along the supply side). Tax stamps have the advantage of being secure (difficult to copy) and are well known in many countries around world. Upgrading existing tax stamps to incorporate a tracking functionality would generally be easier than developing a new tracking and tracing system from scratch.

For many years, tax stamps were nothing more than simple pieces of paper primarily meant to confirm tax paid status of a product, with no unique identification number, no serialisation and few security features. More recently, with the advent of more sophisticated secure printing, substrate formulation and advanced scanning technologies tax stamps have become much more offering a distinct material security layer that can be adapted and utilised with conventional digital tracking and tracing (best practice according to ISO 16678:2014[39]).

Based on these innovations and considering what is offered by most tax stamps today, the gap to fulfil Art. 8 requirements is a relatively small one.

The fundamental difference between a directly marked (printed digital solution) and a traceability solution based on a tax stamp (applied material and digital solution) is that the tax stamp can serve as both the data carrier of the unique identification number and the base for the security features – in other words, using the same physical tax stamp, and simply adding additional features like a unique number and other overt, covert and forensic security features to it. In the instance where there is an existing tax stamp solution (as is the case for many FCTC signatory countries), the rationale for using this as the traceability solution becomes even more compelling as:

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[38] https://www.tax-stamps.org/news-article/viewpoint-tax-stamps--on-the-authentication-front-line
[39] https://www.iso.org/standard/57391.html

1. Introducing a unique identifier and required data elements to the tax stamp would be well within the capabilities of most sophisticated tax stamp solutions. Introduction of this UID would make the solution fully track and traceable;

2. The infrastructure and technology of applying these marks at the required production line speeds and processes has been established – manufacturers would apply essentially the same stamp, in the same way;

3. Tax stamp ordering, usage, wastage and audit controls would already be established with manufacturers and supply chain operators;

4. Aggregation requirements are easily compatible with existing tax stamp solutions;

5. Procurement, contracting, relationship management and service level agreements would already be established with tax stamp solution provider requiring minimal effort to launch and implement a traceability solution.

Section 10 elaborates on how an existing tax stamp regime can be converted to be compliant with Protocol Art.8.

d) Linking the Protocol with Enforcement

The development of enforcement strategies to complement the implementation of the Protocol is highly contextual, and it is critical for administrations to adopt an approach that is responsive to their particular local conditions because "illicit trade" manifests in many different ways and is constantly evolving.

The Protocol contains a number of enforcement-specific provisions, the majority of which are compulsory, largely relating to the use of special investigative techniques, the destruction of confiscated tobacco, the creation of a range of criminal offences, and the use of civil and criminal liability for contraventions.

Enforcement-related Protocol provisions in brief[40]
Compulsory provisions – Parties _must_ introduce the following:
▪ Article 14: Unlawful Conduct and Offences: Adoption of legislative and other measures necessary to establish a range of activities and conduct as unlawful;
▪ Article 15: Liability of legal persons for activities and conduct stipulated as unlawful under Article 14;
▪ Article 16: Prosecutions to ensure that natural and legal persons are subjected to effective, proportionate and dissuasive criminal or non-criminal sanctions, including monetary sanctions;
▪ Article 18: Disposal or destruction: All confiscated tobacco must be destroyed using environmentally friendly methods;
▪ Article 19: Special investigative techniques: Use of controlled deliveries and, where appropriate, the use of other special investigative techniques, such as electronic or other forms of surveillance and undercover operations.
Voluntary provisions – Parties _may choose to_ introduce the following:
Article 17: Seizure payments: Levying an amount proportionate to lost taxes and duties on a liable party.

Implementing the Protocol will contribute significantly to curbing illicit cigarettes, but the provisions are not self-policing, and cannot curb illicit trade in and by itself. A strong enforcement capacity will

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[40] For complete text see the relevant Protocol sections in Annex

always be required as part of efforts aimed at curbing illicit trade: it is how a Party validates the integrity of the system and detects tampering; and ensures compliance with a manufacturer's other customs and excise obligations. It is how a Party detects whether there are illicit packs on the market, and how it traces illicit packs back to their source, or pinpoints where they were diverted from the legal supply chain into the illicit one. Enforcement is how a Party finds unlicensed manufacturing plants, how it figures out whom contraband sales are funding and how those profits are being laundered, and how perpetrators are brought to justice through prosecutions.

Enforcement activities

Across the enforcement paradigm, there are a number of functional and organisational design considerations that are required to properly give effect to the provisions of the Protocol in general, and Article 8 in particular. These include a range of functions, activities and capabilities across the tobacco value chain, for example:

- The ability to audit and validate compliance with the various obligations imposed under the Protocol;
- Checking containers for intermingling and hidden consignments; monitoring other potential smuggling channels; operating non-intrusive inspection tools like scanners and detector dogs;
- Market surveillance; detecting illicit packs on the market; monitoring sales channels for contraventions; and if found, tracing illicit packs back to their origins;
- Cooperating with other agencies to secure evidence and prosecutions;
- Using information from other tax types against which to validate excise-related declarations; assessing the knock-on effect of excise duty evasion on other taxes; and the identification of more sophisticated tobacco-related tax evasion schemes beyond just the under-declaration of excise duties and VAT.

These should be underpinned by a strong business intelligence capacity that has the ability to identify and target both higher risk consignments and entities; and which is closely linked to a management information system that tracks trends over time and has the ability to identify anomalies and outliers for follow-up.

Enforcement activities are, on the whole, more expensive than upstream preventive activities (for instance like production controls at a factory or know-your-customer requirements.) While a strong enforcement capacity is critical, it is not a replacement for more cost-effective upstream controls.

Enforcement blind spots

Enforcement activities globally tend to have a number of blind spots, which are exploited. These include limited overview, oversight or checks in respect of cigarettes manufactured in duty free zones, and cigarettes ostensibly manufactured for sale in duty free channels. The relatively lax controls that are often a feature of these categories result in them constituting an easy source of cigarettes for the illicit market. Key policy and operational changes may be required to ensure that cigarettes manufactured in free trade zones, and for sale in duty free channels, are subject to the same rigorous production controls and traceability as other cigarettes.

Another blind spot lies in governments' use of intelligence: academically speaking governments should refrain from using any intelligence or evidence provided by the tobacco industry against

competitors. In practice, however, given the very limited intelligence capacity government agencies typically have, it is a reality that they do often end up relying on information from within the industry. Governments should be extremely cautious about using information provided by the industry itself, particularly where that information is intended to secure enforcement action against a competitor and should note that there are substantive indicators around the failure of cooperation agreements with industry.[41]

Questions you should be asking

- Capacity and maturity: What capacity do we have internally to conduct checks, audits, inspections, and investigations? What technologies do we have that could compensate for limited human capabilities?
- Cooperation and partnerships: What capacities, legal powers and data do other enforcement agencies have that we could leverage?
- Also see the key questions under the section on estimating the size and nature of illicit trade.

Enforcement Checklist

	CRITICAL SUCCESS FACTORS	In Principle	In Practice
Is there a national illicit tobacco strategy that is continuously reviewed and updated?		☐	☐
Do we use special investigative techniques like controlled deliveries?		☐	☐
Have all offences under the Protocol been criminalised?		☐	☐
Are there cooperation and partnerships between tax, customs, police, prosecutors, and using intelligence-driven targeting?		☐	☐
Do we use of a wide range of technologies, tools and approaches to ensure integrity of the supply chain?		☐	☐
Are we applying extreme caution in using intelligence provided by industry?		☐	☐

E) MEASURING IMPACT OF TRACK AND TRACE

Output measures relate to tracking how much of what an agency did (for example, the number of audits or inspections), while *outcome* measures relate to tracking what *difference* those activities actually made.

At its simplest level, Parties should adopt measures that let it assess whether it has delivered on the spirit of the Protocol, including the extent to which it:

- Better understands the manifestations of illicit trade, how different types of illicit trade are perpetrated, and what strategies have been used to successfully curb them;

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[41] Luk Joossens, Anna Gilmore, Michal Stoklosa and Hana Ross. An assessment of European Union's agreements with the four major Transnational Tobacco Companies to address the illicit cigarette trade. Tobacco Control 2016; 25:254-260

- Has increased the number of enforcement activities and the success rate of those activities;
- Better targets enforcement activities, through better intelligence, data matching and data mining;
- Has introduced systemic policy changes, to secure better compliance across the industry as a whole, rather than just targeting individual instances of non-compliance, and which allows it to target risk at an entity-wide level, instead of targeting risk at a consignment or transactional level, and that increase the barrier of entry for operators in the illicit supply chain;
- Successfully coordinates and cooperates with other agencies; and
- The impact it has on identifying and disbanding syndicates, crime groups or sophisticated tax evasion schemes, beyond just taking action in individual cases.
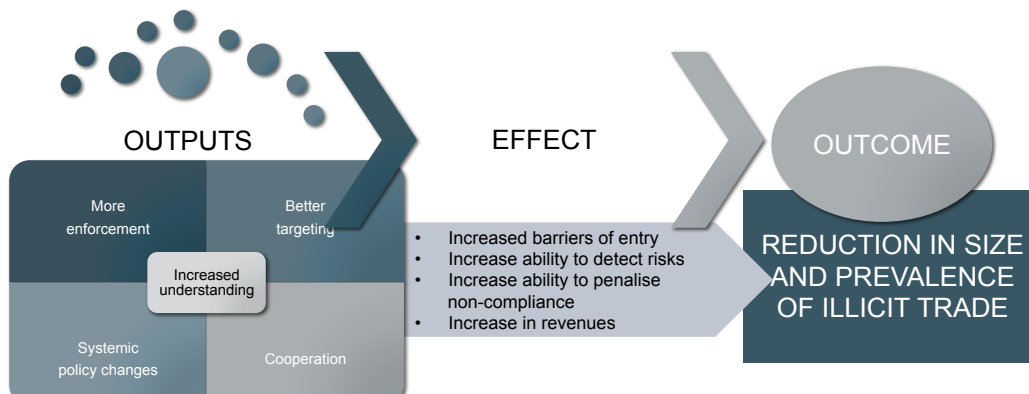
Figure 23: Measuring the Impact of a Track and Trace Solution

Examples of output measures could include an increase in the number of audits conducted at manufacturing premises; an increase in the number of cases submitted for prosecution; an increase in the value of additional assessments or customs schedules issued; and an increase in the number of cooperation or information requests finalised within an agreed period of time.

Examples of outcomes measures could include at a lower operational level, the number of convictions, an increase in the taxes and duties declared by tobacco supply chain actors, the number of syndicates disbanded (as opposed to simply individuals) etc.; and at a macro level, a reduction in the size and prevalence of illicit trade.

9   PUTTING IT ALL TOGETHER

Many governments are signatories of the Protocol and coupled with the health, fiscal, trade and enforcement drivers, a track and trace solution for tobacco becomes a national priority in the fight against illicit trade.

There are 2 scenarios that will most likely prevail for governments:

A. Government has an existing fiscal marking programme and will expand such a program to include the requirements for a secure track and trace solution.
B. Government has no marking program or an ineffective program with limited control of tobacco supply chain and will introduce a track and trace program from scratch.

For scenario A, the journey to expanding or modifying an existing track and trace program is significantly underway, with a large portion of the Protocol requirements able to be addressed by most of the sophisticated fiscal marking programs in operation. Section 10 below details such a case study.

Scenario B requires significantly more effort, starting with a dedicated track and trace program within the designated competent authority. Ensuring the program receives the right level of attention from government, is appropriately resourced and funded and receives the necessary backing from political principals will be critical to ensuring its success and ability to withstand the external and internal rigours faced by such a program.

Whichever of the two scenarios prevails, implementation of a traceability solution and better securing the supply chain to guard against illicit trade typically requires a sequence of activities:

- **Analysis**, focusing on understanding exactly what illicit trade looks like in the country in question, to what extent the supply chain needs to be better regulated, understanding the Party's existing capacity and capabilities, and assessing what kind of governance model will be required to implement the project;
- **Design,** which looks at translating the requirements of the Protocol into a solution blueprint that cuts across legislation, technologies, people and processes, and managed using formal project management methodologies;
- **Procurement,** to secure the services of solution providers to deliver on those elements of the solution blueprint that the Party cannot develop or implement itself, which usually includes technologies, but could also include assistance with analytics and enforcement;
- **Delivery,** which works to actually implement the solution, ranging from introducing the necessary policy changes, implementing the required technologies, reengineering relevant processes, integrating the new solutions with existing operational practices, and on an ongoing basis assessing the effectiveness of the solution and whether adjustments are required.

In the final analysis, though, introducing a traceability solution for tobacco products is about far more than simply complying with the spirit of the Protocol – it is about ensuring that cheap untaxed tobacco products do not find their way onto the market, because once they do they both deprive our governments of revenues, and increase the burden on our healthcare systems. For that reason, the ultimate test of traceability solutions are whether they have actually made a difference in better securing supply chains, and not whether they simply technically check the boxes against Protocol requirements.

1 Plan & Analyse

1. Project Governance
Define a model to govern the development of the T&T solution

2. Problem Statement
Extract a clear and concise set of issues that need to be addressed

3. Illicit Trade Study
Conduct a research study of the fraud archetypes & prevalence of illicit trade

4. Diagnostic Assessment
Assess the legislative, people, process, policy and technology capabilities of an organisation including a stakeholder review and supply chain mapping. Establish a current state baseline for monitoring and evaluation

5. Organisational Strategy
Define the strategic objectives, design principles and critical success factors of the programme

2 Design

1. Business Case
Define the high-level operational , technical and tactical requirements as well as the costs and effort required to address the identified issues

2. Solution Blueprint
Design a solution architecture that meets the strategic mandate of the organisation and achieves the CSF's

3. Legislation
Draft a robust, responsive and proportionate legislation

4. Programme Management Office
Mobilise a team that will be responsible for developing, managing and executing the planned initiative. Define and resource monitoring and evaluation

3 Build

1. Market Analysis
Conduct a market analysis of available solution providers and solution offerings

2. Procurement
Offer solution providers opportunity to bid for appropriate solution

3. Appointment and Contracting
Appoint best fit solution provider and draft contract of mutual benefit

4 Implement

1. Implementation Preparation
Policy drafting, capacity building, technology enhancements, process re-engineering, policy review

2. Solution Implementation
Integrate solution into operational and industry environment

3. Monitoring & Evaluation
Measure the implemented solution against original mandate and CSF's, monitor and evaluate noting any deviations and need for adjustment

Figure 24: Track and Trace Program Steps

10   HYPOTHETICAL CASE STUDY: CONVERTING AN EXISTING TAX STAMP REGIME

Adapting an Existing Fiscal Marking Regime to be Compatible with the Protocol

To recall: "Tax stamps are not the same as tracking and tracings tools but can be upgraded to accomplish track and trace functions. A tax stamp is a visible tax stamp, label or mark placed on certain types of consumer goods to show that the applicable excise tax has been paid**.** Tracking is monitoring an item through a supply chain, while tracing is the ability to check where an item has been (from ISO 12931 2012). The objective of tax stamps is the proof that taxes are paid. The objective of tracking and tracing is to tell the past, current and future locations of products. Tax stamps are applied on products of the domestic market, but not exported products, unless the exported market requests tax stamps. Sophisticated tax stamps have a trace characteristic (telling where the cigarettes come from), but in most cases not a tracking characteristic (there is no aggregation between packs, cartoons and master cases and there is no tracking of the product along the supply side). Tax stamps have the advantage to be secure (difficult to copy) and are well known in many countries around world. Upgrading the actual tax stamps with a tracking functionality is for most finance or enforcement officials easier than to invent a new tracking and tracing system. "

For a traceability solution aligned with Art.8 of the Protocol, Parties would have control of the unique identifiers used at the time of tobacco product manufacture (this could be achieved by delegating this function to an independent 3rd party solution provider), a key risk point for a tobacco control regime. The solution would require the fiscal marking (label, banderol or tax stamp) to be enhanced to include

a secure serialised number, making each label uniquely identifiable. The coding and serialisation for the traceability solution takes place at the time the tax stamp is produced.

At the time of tobacco manufacture, the secure label / stamp would be applied using similar application process as used for tax stamps today. However, a validation system would be installed on the production line and would perform a dual function (The tax stamp solution provider or other solution provider independent of the tobacco manufacturer operates this validation system). In addition to a quality control function to verify that the security feature has been correctly applied, the validation system would also record/capture the unique identifier of each label. It would be able to record the time, manufacturing facility, production line (based on which facility and production line the camera was installed), as well as the product brand and stock keeping unit, thereby creating a complete electronic record of the data elements required at the time of manufacture in terms of Art.8.4 of the Protocol. This information would be uploaded on a near real-time basis to either the Competent Authority or their designated solution vendor store enforcement and reporting access. It must be noted that some information may be protected by privacy regulations and may need to be housed within the premises of the Competent Authority.

The Party would also be accountable for prescribing the security features and the minimum information that should appear on tobacco packs, as well as markings for cartons / bundles, master-cases and pallets for interoperation of the traceability solution. The method for marking of secondary and tertiary packaging is operated by the tobacco manufacturer, together with the aggregation recording mechanisms. The traceability data related to the products is therefore created and managed by the independent provider, whilst the data related to aggregation of the products into packaging for shipment is recorded by the tobacco manufacturers, with an opportunity for integrity of the solution to be verified by reconciling the two.

Supply chain operators would use existing technologies and systems to record logistic event updates as tobacco products move through the distribution chain, and this data is uploaded and provided to the independent data management operator using open industry standards (prescribed by the Party).

Authentication and oversight by Party authorities is enabled by independent control of traceability data generated at the time of manufacture, and through supply chain events recorded from supply chain operators. Enforcement agencies use traceability tools developed by the independent solution provider to read and decode pack markings and access tobacco tracing information.

This proposed solution architecture does constrain the information that can be encoded offline as part of the unique identifier code itself (to that which would be known at the time of secure label production, and might include items such as the manufacturer, product type, intended country of sale), however the additional data (such as production date and time) can be recorded and systematically linked to the unique identifier on the label / stamp at the time of manufacture.

This solution offers a reduced capital investment required from manufacturers to equip tobacco-manufacturing lines, whilst leveraging existing technology, infrastructure, relationships and other solution elements already in place.

Transitioning the Tax Stamp to comply with a Traceability Program

The section below details – at a high level - what specific changes will be required to transition an existing tax stamp to a Protocol Art.8 compliant one looking at the gaps between what is required and what is in place.

Tax stamp prior to Protocol requirements:

Figure 25: Basic Tax Stamp

The hypothetical existing basic tax stamp is produced from unsecured substrate with a single overt security feature in the form of a hologram, sequentially numbered identification code at product level and no covert features. The purpose of this hypothetical tax stamp is primarily for revenue collection purposes with minimal authentication to dissuade unsophisticated illegitimate traders from duplication.

In addition, it must be noted that tobacco products manufactured for export (and this not taxable) usually do not carry tax stamps unless they are exported to a country which requires them. In this case, the tax stamp is applied at the moment of manufacturing. However, the point of importation/exportation of cigarettes is often the moment when most concerns regarding illicit activities arise. In an effort to close these potential blind spots exported cigarettes should be required to carry export labels. Brazil, for instance, has a tax stamp programme, but in addition also requires that exported cigarettes be labelled with an export stamp.

Introducing the Protocol requirements:

Unique Identifier: This would entail converting the current markings to a uniquely identified marking based on the data elements specified by Article 8.4.	
FROM : PRODUCT 123 XYZ	**TO :**
Serialisation: The UID would be applied to the tax stamp is non-sequential, non-repeatable form and will be affixed to every unit pack.	
FROM : Same code on every pack per product	**TO :** Unique code per pack
Security Features: The single overt hologram will be enhanced by adding additional overt, covert and forensic security features. There is a plethora of security features available for application on a tax stamp, from the substrates used, to security inks, to taggants and fingerprinting. Governments can select the best functional vs. cost vs. efficacy combination of security features to suit their particular needs.	
FROM : Basic Hologram Basic Substrate Normal Ink	**TO :** Sophisticated Hologram Sophisticated Substrate Secure Ink

Protocol-compliant tax stamp (sample):

Figure 26: Protocol Compliant Tax Stamp

The Protocol-compliant tax stamp would be fully secured with overt, covert and forensic features, a unique identification code that is machine readable and linked to the database for authentication. **Error! Reference source not found.** 27 at the left highlights elements of the traceability solution that will already be covered by an existing tax stamp solution (green highlight) and elements that would be introduced for any type of traceability solution (blue highlight).
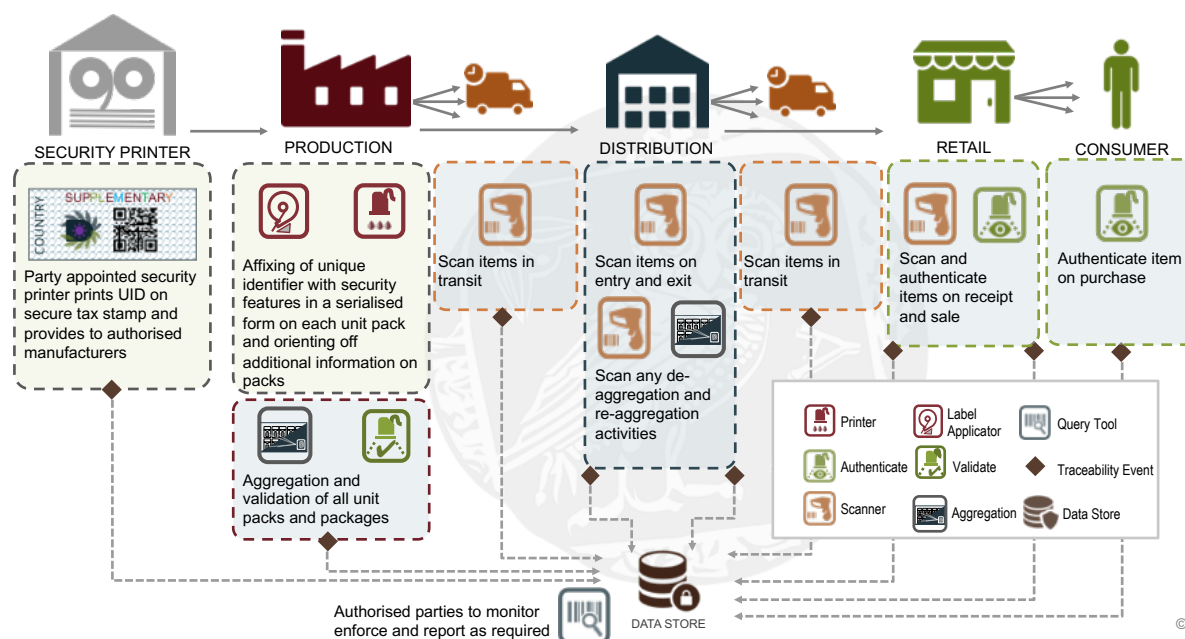
Figure 27: Tax Stamp Traceability Solution

In summary:

1. The tax stamp for the domestic market and an export stamp for the export market will be produced by the Party's choice of security printer or national printing authority, combining the unique identification and security features requirements of Art.8.

2. As the tax stamp and the export stamp is the data carrier for the UID, the security printer, national printing authority or another party will be responsible for printing the unique identifier (variable data) onto each label using Party-specified technical standards in terms of method for code generation, how a machine readable code is represented (such as ECC data matrix or ISS dot code), and how the event data is recorded and submitted.

3. The secure tax stamp and the export stamp with unique identifier would then be provided to the tobacco manufacturers for application to the tobacco products during the manufacturing / finishing processes.

4. The aggregation markings (labels or directly printed) would be linked to the UID and would serve as the traceability mark for supply chain events.

5. Enforcement agencies and other authorised parties may intervene at any time in the supply chain to perform authentication or track and tracing of products.

6. Data would be available for query or global sharing as required.

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The alternative to utilising an existing tax stamp programme would be to introduce a new track and trace solution on top of the existing tax stamp program. There would be significant overlap of function, not to mention the added enforcement burden on customs and excise having to manage 2 solutions. A directly printed track and trace solution (with requisite UID, serialisation, security features and authentication capabilities) could theoretically replace the tax stamp, but it is difficult to advance a business case on what benefit this would have[42].

Although not directly related to the Protocol, an added advantage of expanding a tax stamp program to a track and trace solution would be the cross-product potential of tax stamps. Many governments have other excise taxes that they impose, like alcohol, sugar-containing beverages, fuel, etc. The framework from a tax stamp solution could be applied to most of other excisable goods and extending the solution to other products based on an established framework and governance model would certainly be beneficial for governments.

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[42] See Kenya case study for benefits of expanding a tax stamp program to track and trace solution: http://www.wcoomd.org/-/media/wco/public/global/pdf/media/wco-news-magazines/wconews_75.pdf

11 ADDITIONAL RESOURCES/REFERENCES

11.1 ANNEX 1: SUPPLY CHAIN SECURITY OBLIGATIONS ON A GOVERNMENT-TO-GOVERNMENT BASIS

FCTC PROTOCOL: OBLIGATIONS IMPOSED FROM A GOVERNMENT-TO-GOVERNMENT PERSPECTIVE	
Article 4: General obligations	▪ Regional and international cooperation ▪ Ensure maximum transparency of any interactions with the tobacco industry
Article 8: Tracking and tracing	▪ Make information accessible to the global information-sharing focal point on request through a standard electronic secure interface ▪ Only request information from the global information sharing point where it is necessary for the detection of investigation of illicit trade ▪ Not unreasonably withhold information from the information sharing point ▪ Answer information requests ▪ Obligations may not be performed by or delegated to the tobacco industry ▪ Interact with the tobacco industry only to the extent necessary ▪ May require the tobacco industry to bear associated costs
Article 9: Record-keeping	Establish a system for sharing details in records and cooperate to develop improved systems for record-keeping
Article 20: Information sharing	▪ Report details of seizures and taxes evaded; quantities and values of tobacco and manufacturing equipment manufactured, imported, transited, tax-paid and duty-free sales; trends, concealment and modus operandi used
21: Enforcement	Exchange information on licensing records, identities of persons involved in illicit trade, records of investigations and prosecutions, records of payments, details of seizures
23: Cooperation	▪ Cooperate in providing training, technical assistance and cooperation in scientific, technical and technological matters, including the transfer of expertise or technology for information gathering, law enforcement, tracking and tracing, information management, protection of personal data, interdiction, electronic surveillance, forensic analysis, mutual legal assistance and extradition. ▪ Develop and research the identification of the exact geographical origin of seized tobacco
24: Investigation and prosecution	Cooperation and information exchange between administrative, regulatory, law enforcement and other authorities for prevention, detection, investigation, prosecution and punishment for persons involved in illicit trade
27: Law enforcement cooperation	Channels of communication between competent authorities and agencies for secure and rapid exchange of information; cooperation in conducting enquiries; providing items for analytical or investigative purposes; exchange of personnel and experts and liaison experts; exchange information on means and methods used in committing offences including e.g. routes, conveyances, the use of false identities, altered or false documents.

11.2 ANNEX 2: PROVISIONS FOR SUPPLY CHAIN ACTORS

FCTC PROTOCOL: BASIC PRINCIPLES RELATED TO SUPPLY CHAIN SECURITY

Article 6: Licensing	▪ Manufacture, import and exports of tobacco products and manufacturing equipment requires a licence ▪ Licensing conditions should include providing information on identify, location of premises, products manufactured, equipment used, previous criminal records, banks accounts to be used, intended market of sale which includes showing that manufacturing is commensurate with reasonably anticipated demand. ▪ Audit licences to prevent, detect and investigate fraudulent practices ▪ Periodic reviews, renewals and audits of licences ▪ Expiration of licences and reapplication processes ▪ Notification of change of location or activities ▪ Reporting of the acquisition or disposal of manufacturing equipment ▪ May choose to licence retailers, growers, transporters, wholesalers, brokers, warehousing ▪ [to be augmented by further research to assess whether key inputs into the manufacturing process – line filters and paper – can be subject to effective controls, after which this may be further strengthened]
Article 7: Due diligence	▪ Everybody in the supply chain must conduct due diligence before commencement and during course of business relationships, which includes know-your-customer requirements, monitoring sales to ensure quantities are commensurate with demand in the intended market of sale, and reporting any evidence that a customer contravenes its obligations ▪ Due diligence may include requiring customers to declare criminal records and provide details of bank accounts, ▪ May designate certain customers as "blocked customers"
Article 8: Tracking and tracing	▪ Establish a tracking and tracing system controlled by government for all locally manufactured or imported tobacco products ▪ Require information that is incorporated into unique identification markings at the time of production or at the time of import, that assists to determine the origin of tobacco, the point of diversion, monitor and control the movement of tobacco, and their legal status [with a comprehensive list of information required detailed in art. 4.1] ▪ Provide information in the format prescribed through a standard electronic interface ▪ Track and trace up to the point that all duties and taxes have been discharged ▪ Obligations may not be performed by or delegated to the tobacco industry ▪ May require the tobacco industry to bear associated costs
Article 9: Record- keeping	▪ Provide complete and accurate records of all transactions which includes full accountability for all materials used in the production of tobacco products ▪ Provide on request information on market volumes, trends, and forecasts, and on quantities of tobacco products and equipment ▪ Provide information on tobacco products and manufacturing equipment at the time when the goods depart from their control status [with a comprehensive list of information required detailed in art. 9.3] ▪ Maintain all records for at least 4 years, and in the format prescribed ▪ May require retailers and tobacco growers to maintain complete records of all transactions
Article 10: Security and preventive measures	▪ Require all persons to take necessary measures to prevent diversion of tobacco into illicit channels including reporting the cross-border transfer of cash and cross-border payments in kind; and supplying tobacco only in amounts commensurate with the demand in the intended market of retail sale ▪ Payments may only be made in the currency and the same amount as the invoice, and only using legal modes of payment from financial institutions in the intended market and may not be made using any alternative remittance systems.

	▪ Criminal, civil or administrative procedures and effective proportionate dissuasive sanctions including suspension or cancellation of licences ▪ May require that payments for materials used in the manufacture of tobacco products may only made in the currency and the same amount as the invoice, and only using legal modes of payment from financial institutions in the intended market and may not be made using any alternative remittance systems.
Article 11: Internet sales	▪ All internet-, telecommunication-, or other technology-based modes of sale must comply with all of these obligations' ▪ May ban the retail sale of tobacco products through internet-, telecommunication-, or other technology-based modes
Article 12: Free zones and transit	▪ Effective controls on all manufacturing of and transactions in tobacco and tobacco products in free zones using the measures in the Protocol ▪ Not intermingling of tobacco products with non-tobacco products in a single container or other similar transportation unit at the time of removal from a free zone ▪ Apply control and verification measures to transit or transhipment of tobacco products and manufacturing equipment to prevent illicit trade
Article 13: Duty free sales	▪ Duty free sales are subject to these provisions ▪ [to be augmented by further research into the extent of illicit trade related to duty-free sales, after which this may be further strengthened]
Article 14: Offences	Adopt measures to criminalise a series of conduct based on the provisions above [with a comprehensive list of information required detailed in art. 14]
15: Liability	Establish liability for legal persons for unlawful conduct
16: Sanctions	Maximise discretionary use of legal powers including the use of prosecutions
17: Seizure payments	May levy an amount proportionate to lost taxes and duties from producers, distributors, importers or exporters of seized tobacco and manufacturing equipment
18: Disposal	All confiscated tobacco, tobacco products and manufacturing equipment to be destroyed using environmentally friendly methods, or disposed of in terms of national law
19: Investigative techniques	Use of controlled deliveries and other special investigative techniques like electronic surveillance and undercover operations (in accordance with domestic law) Leveraging bilateral or multilateral agreements or arrangements

11.3 ANNEX 3: TYPES OF SECURITY FEATURES

A) OVERT

Overt security features are apparent, immediately visible and can be verified by the naked eye (or human senses) without any additional equipment or devices. These security features are most suited for consumers or retailers to authenticate a product as legitimate and ideally should **require no (or minimal) training** and the security feature should **provide a clear and unambiguous result**. The following table outlines the different types of overt security features:

Security Feature	Description
Barcode and Product Coding	A barcode is a series of vertical printed bars of controlled thickness and separation representing variable data information in a linear format. A 2D barcode consists of a

	representation of solid and clear images (usually squares) in a matrix format over a specific two-dimensional structure. Barcodes and code verification services are sometimes marketed as an overt (or "digital") security feature, but in standard form offer no protection against reproduction, making this relatively weak when used in isolation.
Colour Shifting/Changing Inks	Optically variable inks offer a visible colour-shifting effect, changing colour when viewed at different angles. Advantages include instant verification. They can easily be used on tobacco packaging and are often found on banknotes. These inks are fairly secure but there are similar effects that can be created using substitute materials (e.g. nail varnishes and auto paints). Applying photonic colour offers enhanced optical effects beyond that of optically variable inks, including iridescent effects. Since they do not depend upon pigments or dyes, they deliver brighter colour.
Holograms	Holograms are optically variable images created through the interference of two laser beams. Holograms are the most common type of diffractive optically variable devices. There are two classifications of holograms: embossed holograms, which are holograms stamped onto metallised foil, and reflective holograms that form an image by reflected light. It is possible to copy embossed holograms if they do not have additional features, such as concealed images, guilloche patterns, taggants, serial numbers, kinetic images, microtexts, etc. Embossed holograms are typically lower cost, but the use of reflective holograms may be considered somewhat more secure because the film needed to manufacture reflection holograms is more controlled with limited availability.
Hot and Cold Foil Stamping	Hot and cold foil stamping involves the use of heavy embossing dies in combination with hot or cold applied foil. It is effective because foil is reflective, and its metallic effects cannot be copied. Hot foil stamping also has properties that include high abrasion, scratch and temperature resistance. Holograms can also be used on the foils.
Other Optically Variable Devices (OVDs)	OVDs are visible features with dynamic characteristics that change according to the viewing angle, for example from one colour to another, or from one image to another. OVDs are similar to holograms but can include other devices such as image flips, or transitions, often including colour transformations or monochromatic contrasts.
Security Threads and Fibres	Security threads are polyester threads that are either fully or partially embedded down the length of the paper. Fully embedded threads can only be viewed when the document is held up to the light. Partially embedded threads appear intermittently on one side of the paper. Security fibres are small fibres randomly distributed throughout the paper while it is still in the pulp form. The fibres may be coloured or have fluorescent dyes only visible under UV light.
Watermarks	A watermark is an image in paper produced by varying the thickness and density of the paper mass during paper production. These variations form a distinguishable image that can be viewed when holding the paper item up to the light.

B) SEMI-COVERT AND COVERT

These following **semi-covert** security features require a simple tool and minimal training to authenticate the product:

Security Feature	Description
Latent Images	Hidden image technology (HIT) embeds an image in the print on a product. These effects can be created for detection by tilting the printed image in a particular manner, by means of using a simple validation device.
	A latent image detected by means of tilt is created by printing certain elements of the image with a special raised ink. Looking directly at the printed image, it is not apparent that some ink elements are slightly raised compared to others, but as the printed image is tilted and viewed at an angle, the raised ink becomes apparent, obscuring the non-raised printed elements to create a visual effect.
	A covert feature can be created by embedding visual artefacts in the image that can only be seen by a special optical lens (film overlays such as polarising filters). This lens allows only specific areas of the image to be revealed at any one time. As the inspector moves the filter around and finds the correct alignment, the part of the image containing the hidden digitised image becomes visible. The hidden section scan shows different images as the lens rotates.
Security Inks	Thermochromic inks: Inks that change colour when exposed to a change in temperature (hot or cold). It is used primarily on food and beverage products.
	Photochromic inks: Inks that change colour when exposed to a UV light source. The inks can be coloured or colourless. The authenticity of a product/document with photochromic ink can also be checked by exposure to sunlight or other strong artificial lights. There can also be a hybrid of the thermochromic and the photochromic inks using cold and sun activation.
	Up-converting or down-converting inks: These inks are colourless and transparent in normal lighting conditions but contain a fluorescent ink that emits light in the visible spectrum when exposed outside the human visible spectrum such as ultraviolet (UV) or infrared (IR) light. A device emitting light in the necessary spectrum to trigger this effect is required to check that this ink is in place. Laser activated inks are similar to this, but only change colour when activated by a very specific frequency of light. For this reason, they are considered more secure than UV or IR inks, but require a more specialised detection device.
	Metameric inks: Inks that appear differently according to the light source. For example, under normal light two items viewed under the same light appear identical, but when using a filter or other special illumination the colours on the items appear different.
	Coin reactive/ scratch-off Inks: The image printed from these inks is white or transparent. The image is revealed when the edge of a coin is rubbed over the ink. This provides for immediate verification of authenticity without the use of any special devices.

The following **covert** security features can be authenticated only by using dedicated and specialised electronic readers for authentication:

Security Feature	Description
Digital Watermarks	Digital data embedded directly within video, audio or print content which is imperceptible to humans but readable by computers. The watermark may be embedded by means of subtle variations in colours, patterns or applied materials (such as varnish applied to printed material).
Forensic Markers/Nano-Taggants	Forensic markers are molecular or microscopic particles that can be organic or inorganic in composition and exhibit specific and unique physical, biological, or chemical properties. They can be embedded into different aspects of the security

	features on a product, (e.g., holograms, security threads, etc.) Forensic markers are highly secure, but also high in cost and may be hard to control in multiple markets. All of the above inks can be further enhanced by the addition of covert forensic markers in nanotechnology formulation.
Radio Frequency Identification Device (RFID)	RFID's are small microchips containing, or able to contain, unique and individual information related to the item to which the chip is attached. The chip, and therefore the information, is addressed by means of radio waves which are conveyed to the chip by means of an attached antenna. These devices are now so small that they can be neatly implanted into plastic cards or paper. They can typically be detected at distances ranging from a few millimetres to several meters.
Security Inks	Magnetic inks: These inks contain small iron oxide magnetic flakes and allow a number to be machine read. The inks have two filmic layers, one carrying an invisible (magnetic) image and the other an invisible magnetisable layer. Magnetic inks are mainly used for serialisation and numbering purposes but are also found in base security inks within banknotes.
	Conductive inks: A conductive ink results in a printed object which conducts electricity. These inks allow circuits to be drawn or printed on a variety of substrate materials such as polyester to paper. This can result in optical effects, such as flashing 'lights' or to make covert messages visible.
	Biometric inks: Biometric inks contain DNA taggants that can be machine read or react to a reading solvent. This allows for verification of a genuine product. These are completely covert but require specialist methods to validate the authenticity. There are optical machine-readable taggants that require a UV/IR light energy reader – if the wavelength response matches the calibration of the reader then the ink is authentic. There are also magnetic based taggants that are a physical based system, not chemistry based. A handheld device, similar to MRI, is used to authenticate inks.

11.4 ANNEX 4: DATA MANAGEMENT REQUIREMENT DETAILS

A) HIGH CARDINALITY (REFERRING TO THE NUMBER OF PRODUCT ITEMS REQUIRING TRACEABILITY)

The tobacco domain is probably second to only the postal domain in terms of number of items that require tracking. More than 6 trillion tobacco items are manufactured globally annually[43]. As a comparison, the RAPEX[44] (EU rapid alert system for dangerous consumer products) system is managing a few thousand notifications per year (2364 notifications in 2013).[45]

Relational database management systems (RDBMS) have long been the only serious candidates to store and query large amount of data, and traceability is no exception. The large majority of these databases are based on the Syntax Query Language (SQL) which is largely documented, available and understood by the IT community and is still today the most widely used database language since its inception around the seventies.

Some suppliers are starting to consider alternative data storage and technologies to overcome some of the challenges presented by the growing amount of data that item-level serialisation represents, especially in scenarios where the data captured along the supply chain is inflating the data by an order of magnitude.

B) HIGH-AVAILABILITY

The tobacco industry operates in real-time, almost around the clock, meaning their production process demands a track and trace solution that can match the speed and availability of their production lines. The same applies from an enforcement perspective, where agencies will require information to be available as and when requested for authentication or reporting purposes. This implies a data management infrastructure and interface that can meet those demands.

This is usually done through the implementation of fail-over and redundancy mechanisms (a procedure by which a system automatically transfers control to a duplicate system with almost equal data when it detects a fault or failure) of the critical components to avoid a single point of failure (SPOF) at all levels of the system. If some point may tolerate degraded quality of service or even temporary failure, this should be clearly identified, and the consequences carefully evaluated. In no way it should allow breaking the chain-of-custody of the data and putting the integrity of the system at risk.

C) DISTRIBUTED BY NATURE

As for any fast-moving consumer goods product, the tobacco supply chain is large and distributed both geographically and between entities (manufacturer, wholesaler, distribution and retail). It means that information is not kept on a single database and must be shared between instances by passing messages through a network, which, under normal circumstances, is faster than the speed at which the goods are travelling.

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[43] https://www.verywellmind.com/global-smoking-statistics-for-2002-2824393

[44] https://en.wikipedia.org/wiki/Rapid_Exchange_of_Information_System

[45] Punishing for Safety - http://ec.europa.eu/consumers/safety/rapex/reports/docs/a0_infographic_en.pdf (accessed in 28/04/2014).

D) SUSTAINED DATA INGRESS

A direct consequence of the volume of data is the sustained speed at which the system must store the data, and while not particularly challenging at line or factory level, when taken at country, regional or global level, it can turn into a bottleneck. The datastore, as well as the network, must be dimensioned properly to take this point into account to insure a trouble-free operation, and thus at minimal cost. Buffering, message queuing or enterprise service bus (ESB) can help to cope with temporary loss of connectivity, reduced availability of a critical component and data-exchange between internal and external systems.

E) DATA SECURITY

One of the drivers for having a track and trace system in place is protecting customers as well as legitimate businesses and the revenues they are generating. This cannot happen if critical data circulating in the system (serial numbers, aggregation information, origin, etc.) is vulnerable. Data security is commonly subdivided into the following 4 attributes:

- Confidentiality – is the property that ensures that information is not made available or disclosed to unauthorised individuals, entities, or processes;

- Integrity – is the property that data has not been changed, destroyed, or lost in an unauthorised or accidental manner during transport or storage;

- Availability – is the property of a system or a system resource being accessible and usable upon demand by an authorised system entity;

- Accountability – is the property of a system (including all of its system resources) that ensures that the actions of a system entity may be traced uniquely to that entity, which can be held responsible for its actions.

Data security techniques like encryption, authentication, digital signatures, and non-repudiation services (provides proof of the origin of data and the integrity of the data), must be applied to data to provide or augment the system attributes described above. Since the whole system is as strong as the weakest of its components, additional control must be applied at other relevant levels (physical and environmental security, access control, network and communication etc. This is addressed with the standard ISO 27001).

F) MASTER DATA MANAGEMENT INTERFACE & SERIAL GENERATION

Also derived from the asynchronous and distributed nature of the supply chain, there is the need for a master data management (MDM) system which will insure, for example, that several manufacturing facilities that are attributing the same code to designate the same product, which is a necessity when a product can be manufactured in several sites or that a code indicating a location is not used twice for different places.

Master data is additional data that provides the necessary context for interpreting the elements of the event data (such as interpreting the identifier of a specific production line and being able to reference the physical address of the facility). In contrast, the event data arises in the course of carrying out business processes and grows in quantity as the items are progressing along the supply-chain.
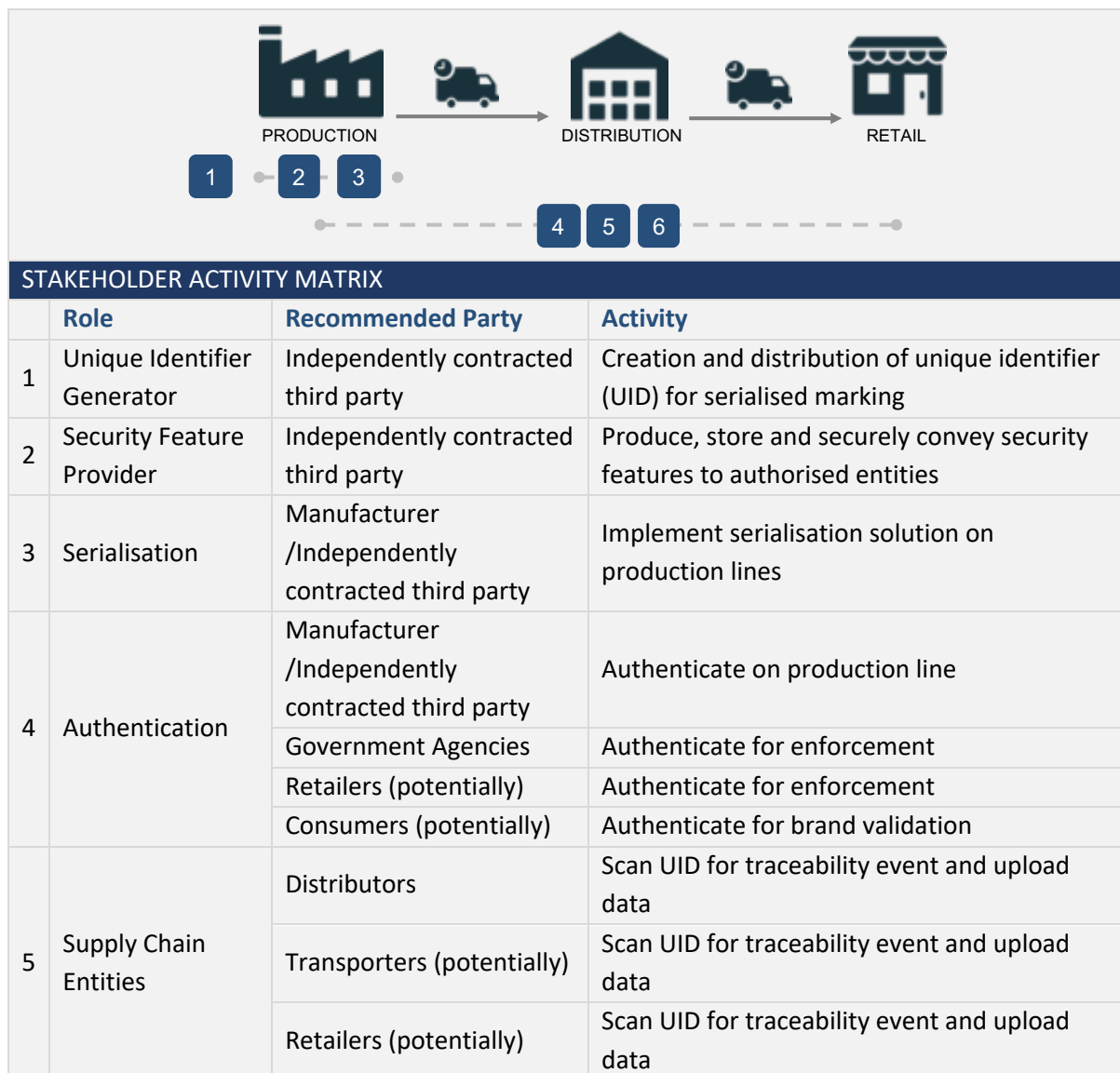
It is critical that the master data management role is independent of industry, as this role would be responsible for defining, generating and maintaining the integrity of the serialised code generation that will be used to mark each item. It is recommended that this role be played by the government authority or its designated contractor.

G) MONITORING, INCONSISTENCY DETECTION & RECONCILIATION

Often overlooked, this is a fundamental aspect of traceability implementation. A carefully designed rule-driven system preferably with government oversight (routing of incorrect data above a certain threshold, alert and escalation, etc.) is recommended to maintain a high standard of quality data and promote the adhesion to good serialisation practices. Having reliable data transiting from one source (manufacturer, distributor) to the next (wholesaler, distributor) is essential to maintain the integrity of the aggregated data.

11.5 ANNEX 5: STAKEHOLDER ROLES/ACTIVITIES IN THE SUPPLY CHAIN

STAKEHOLDER ACTIVITY MATRIX			
	Role	**Recommended Party**	**Activity**
1	Unique Identifier Generator	Independently contracted third party	Creation and distribution of unique identifier (UID) for serialised marking
2	Security Feature Provider	Independently contracted third party	Produce, store and securely convey security features to authorised entities
3	Serialisation	Manufacturer /Independently contracted third party	Implement serialisation solution on production lines
4	Authentication	Manufacturer /Independently contracted third party	Authenticate on production line
		Government Agencies	Authenticate for enforcement
		Retailers (potentially)	Authenticate for enforcement
		Consumers (potentially)	Authenticate for brand validation
5	Supply Chain Entities	Distributors	Scan UID for traceability event and upload data
		Transporters (potentially)	Scan UID for traceability event and upload data
		Retailers (potentially)	Scan UID for traceability event and upload data

6	Data Management	Independently contracted third party	Create secure, centralised store for all traceability data with back-up, redundancies and fail-over
		Manufacturer /Independently contracted third party	• Create local storage for traceability data • Near real-time upload of serialisation and authentication data
		Distributors	Upload supply chain event data
		Transporters (potentially)	Upload supply chain event data
		Retailers (potentially)	Upload supply chain event data
		Consumers (potentially)	Query database for authentication
		Government Agencies	• Enforcement • Reporting/ statistics • Analysis • Sharing with regional/global portal