Track and Trace

Approaches in Tobacco

Contents

ABOUT KPMG

KPMG LLP is a leading provider of professional services including Audit, Tax and Advisory. We have on average 11,300 partners and staff working in 22 offices across Great Britain.

Since 2005, KPMG LLP has led a Pan European assessment of the scale of counterfeit and contraband tobacco on behalf of the tobacco industry and the European Commission's Anti Fraud Office (OLAF). We have worked extensively with the industry and other stakeholders on developing an approach to illicit market sizing and implementing a common, global approach to illicit trade measurement. We are currently involved in measuring illicit tobacco flows in Latin America, Australia, New Zealand and Oceania.

KPMG's global supply chain and operations practice has over 1,000 consultants specialising in strategy and implementing business transformation. We have deep sector expertise in retail, FMCG, telecommunication and tobacco.

ABOUT GS1 UK

GS1 UK is one of 111 GS1 member organisations serving 150 countries with a combined worldwide membership of close to two million companies.

GS1 is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world and includes the GS1 Global Traceability Standard.

GS1 is a recognized, open and neutral source for the World Health Organisation (WHO), is accredited as an Issuing Agency by the U.S. Food and Drug Administration for Unique Device Identification, has Memoranda of Understanding with The Bureau International des Containers et du Transport Intermodal (B.I.C.), Health Level Seven International (HL7)and the World Customs Organisation (WCO) and is working closely with national customs organisations around the world.

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GS1 UK

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With more than 20 years of consulting experience, Andrew Underwood is the Partner who leads the UK's Supply Chain practice at KPMG. Andrew has led programmes to deliver operational improvement in some of the world's largest FTSE and Fortune companies across a number of sectors, including consumer markets and telecommunications. He has recently been involved in business responses to food contamination and traceability issues in the UK.

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David has more than 25 years experience of managing the development, support and marketing of information and communications based products and services. The application areas that he has covered include international equities and derivatives markets, global financial risk management, international online trading of crude and refined oil products, real-time news, and corporate budgeting and management information systems. David has in depth knowledge of GS1 standards and their application in supply chain and traceability systems. David is the GS1 UK lead consultant on track and trace and has been involved in the development of the EPCIS track and trace standard since its beginning.

Introduction

KPMG and GS1 UK were commissioned to investigate the illicit trade in tobacco and how the FCTC Protocol's requirements for track and trace can most effectively tackle it. We have brought our experience of illicit trade, supply chain management and the development of standards to our research and hope that its findings and recommendations assist in the implementation of these initiatives.

1.1. Introduction

Illicit tobacco deprives governments of tax revenues, undermines efforts to reduce consumption through price increases and undermines other controls on consumption. The preamble to the World Health Organization's 'Protocol to Eliminate Illicit Trade in Tobacco Products' (the Protocol) highlights several themes which run through the subsequent 40 pages of detailed actions to tackle the problem: 'international action', 'cooperation' and the need for 'a secure supply chain for tobacco products'. Illicit tobacco is an international problem which is rightly getting attention, investment and political commitment.

The European Union's revised Tobacco Products Directive will require track and trace in tobacco products. In addition, the four global tobacco majors are each implementing tracking and tracing systems as a result of separate individual agreements with the European Commission and 27 of its member states.

Tracking and tracing is developing rapidly in many sectors with pressure for greater visibility, confidence and transparency. With enhanced IT, the development of smart phone apps, and web-based interfaces (which might allow anyone to play a role in verification), it is a field which is evolving across many consumer and industrial goods sectors.

As countries sign up to endorse the FCTC Protocol, the focus is on the adoption and implementation of its requirements. The Protocol encourages questions such as 'what features make track and trace effective?', 'how can the Protocol's ambitions for global data sharing best be achieved?' and 'how can all the aspects of the Protocol be leveraged to reduce illicit trade?'.

This report focuses on Part III of the Protocol and its aim to control the supply chain in tobacco products through the establishment of a global tracking and tracing regime. The report highlights key learnings on the implementation of track and trace from other industries and provides high level recommendations on how governments can effectively implement track and trace for tobacco products.

1.2. The purpose of this report

This report aims to support implementation of one of the Protocol's key components – the implementation of track and trace in tobacco products, by looking at what features are most likely to make a deployment effective.

The focus of this report is deliberately on the implementation and impact of tracking and tracing mandated through the Protocol.

This report is a result of collaboration between KPMG and GS1 UK and draws upon our expertise in the area of illicit trade, tracking and tracing and supply chain management. We have prepared this report for the Digital Coding & Tracking Association (DCTA), but the views expressed are our own.

We hope that the lessons learnt from deployments of track and trace systems in other sectors can be shared more widely to inform developments in the tobacco industry and that this report assists in that process.
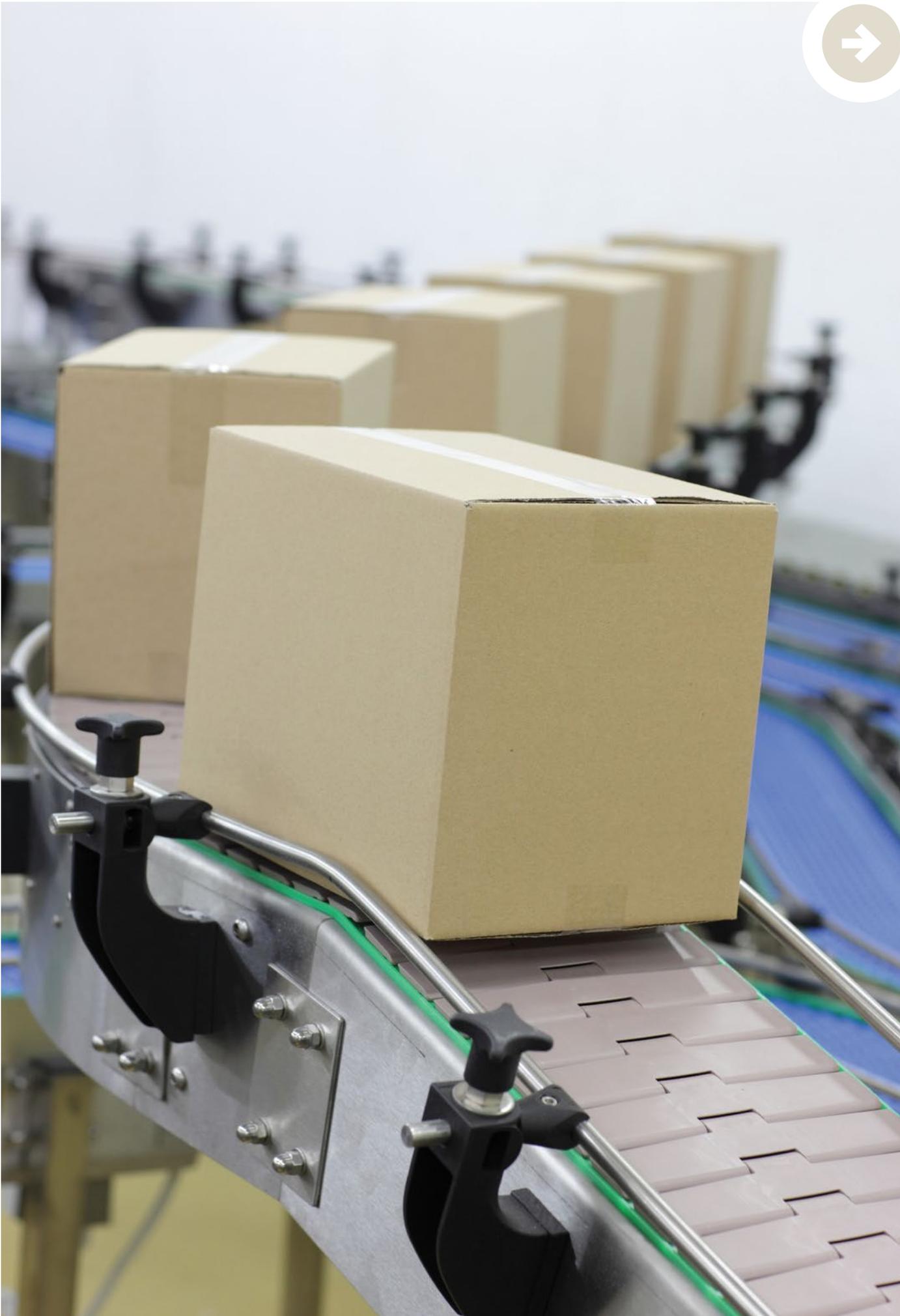
2.1 Key findings

We have reviewed the nature of illicit trade in tobacco and the deployment of track and trace in different sectors.

Illicit trade in tobacco products is a growing source of damage to governments, industry and consumers alike.

The illicit tobacco trade currently accounts for 10-12% of the global cigarette market. As well as having a negative impact on public health, it also undermines tobacco control policies, causes substantial losses to government revenues, undermines legitimate businesses and contributes to the funding of transnational criminal activities. Despite this, countering the trade is made more challenging by a lack of resources.

Track and trace systems have the potential to protect the supply chains in numerous industries.

Track and trace involves supply chain partners recording how an item moves through the supply chain. This allows the location of an item to be determined as well as the history of that item's movement through it. Track and trace systems have been employed by brand owners, manufacturers and governments for purposes such as combating counterfeiting and controlling quality.
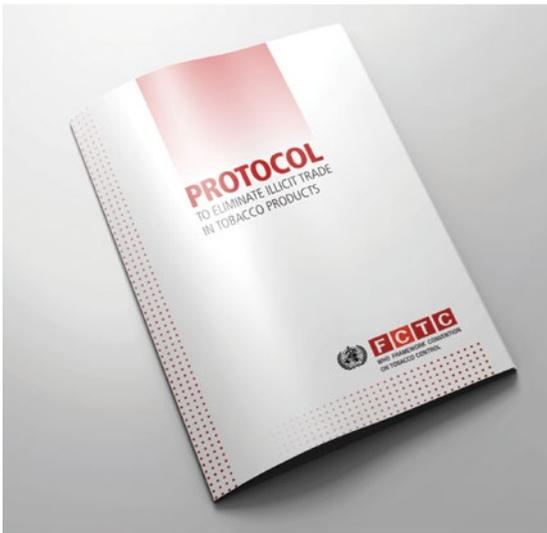
The FCTC Protocol mandates the implementation of track and trace for tobacco products, but stops short of establishing any global standards, and the governance needed to implement it.

The Protocol requires governments to implement national track and trace systems and to collaborate and share the information generated on an international level. The expert review which supported the Protocol went further in highlighting the need for global standards. The Protocol does not exempt smaller businesses from these obligations and it is assumed that tracking and tracing will apply to all tobacco products. However, the Protocol does not attempt to establish a dedicated forum which could create a common set of standards for these systems. This risks generating a patchwork of national deployments which cannot 'talk' to each other.

Experience from other industries teaches us that successful deployment of track and trace systems depends on open standards, pan-industry cooperation and provider competition.

Supply chains as diverse as conflict minerals and pharmaceuticals are benefiting from increasingly sophisticated track and trace systems and there is good evidence that greater supply chain control is possible as a result.

Experience from other industries suggests that:

- Open standards offer significant advantages, driving down cost and increasing adoption rates;
- Basing track and trace systems on existing business processes is likely to promote more rapid and reliable implementation;
- Competition amongst track and trace providers should be encouraged and enabled;
- Pan-regional, or global, cooperation is essential;
- Effective track and trace requires collaboration between industry and regulators alike; and
- A dedicated forum to help develop track and trace guidelines is critical.

The track and trace provider landscape divides into companies with an IT/data processing background and those with a security printing background. The latter group are prima facie less able to meet the full requirements of the Protocol.

Our research suggests that security printing companies are less able to meet the interoperability, aggregation and unique identifier requirements of the Protocol. IT/data processing companies, on the other hand, are capable of gathering data from across a range of supply chain partners, each potentially operating different systems, and tend to encourage open standards.

2.2 Recommendations

Our insights into illicit tobacco and track and trace lead to seven main recommendations. The FCTC Protocol can be an effective tool in tackling illicit trade in tobacco, but we believe that these recommendations are important in ensuring that its provisions on track and trace are successfully implemented.

1

A comprehensive approach is required:

Governments should adopt tracking and tracing as part of a wider programme of anti-illicit trade measures as tracking and tracing without enforcement, data exchange and international co-ordination will not be effective.

2

Open standards are key:

Open standards are key to the implementation of an effective track and trace regime for tobacco products, but there are currently no agreed standards as part of the FCTC Protocol. Open standards:

- ensure interoperability between systems – including between legacy and new systems;
- encourage greater levels of adoption and therefore superior supply chain coverage; and
- drive lower costs of implementation by being system and provider agnostic.

3

Ensure system interoperability:

In adopting a track and trace regime for tobacco products, it is preferable for governments to encourage providers to use open standards to ensure interoperability between different national systems.

4

Establish a dedicated forum:

Currently, there are limited support mechanisms or guidance available for governments to implement track and trace. It will be necessary to establish a dedicated forum involving all stakeholders to lead the establishment of open standards and to develop an architecture for tobacco track and trace that can be adopted by governments. This forum, at a minimum, should include government, regulatory bodies, NGOs, the tobacco industry, standards bodies and enforcement organisations. The forum should also consider delivering a 'base' tracking and tracing system to enable low cost deployments.

5

Cooperation on information sharing:

Cooperation between countries is required to develop effective information sharing about illicit tobacco products.

6

Systems should be flexible:

Governments have to ensure that the adopted track and trace system is flexible enough that it can be adjusted to their needs and requirements and can cope with expected technological changes. They should ensure that systems are capable of practical adoption in smaller businesses within the tobacco supply chain.

7

Ensure competition between solution providers:

Governments should encourage competition in the market by conducting open procurement, allowing multiple providers with varied technologies and service offerings to offer their track and trace solutions, as long as they comply with the agreed open standards.
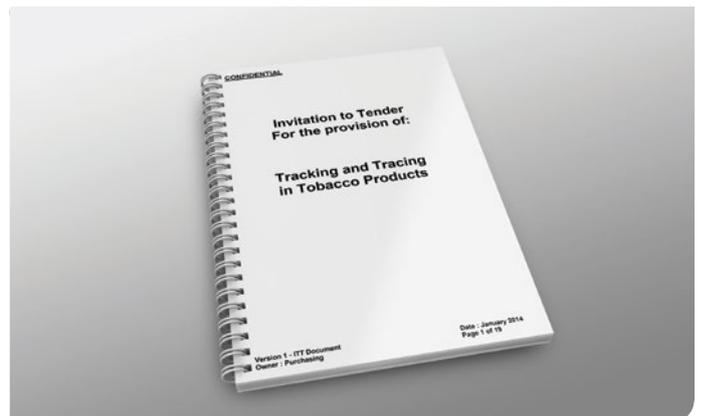
Background to the
illicit tobacco products trade

The trade in illicit tobacco products remains a global phenomenon, affecting both advanced and developing economies on all continents. Despite governments' enforcement efforts, it continues to grow.

Figure 1. Share of illicit cigarette trade by country [1, 2, 3]

Less than 10%	10 - 19.9%	20 - 29.9%	30 - 39.9%	40% and above	No reliable data
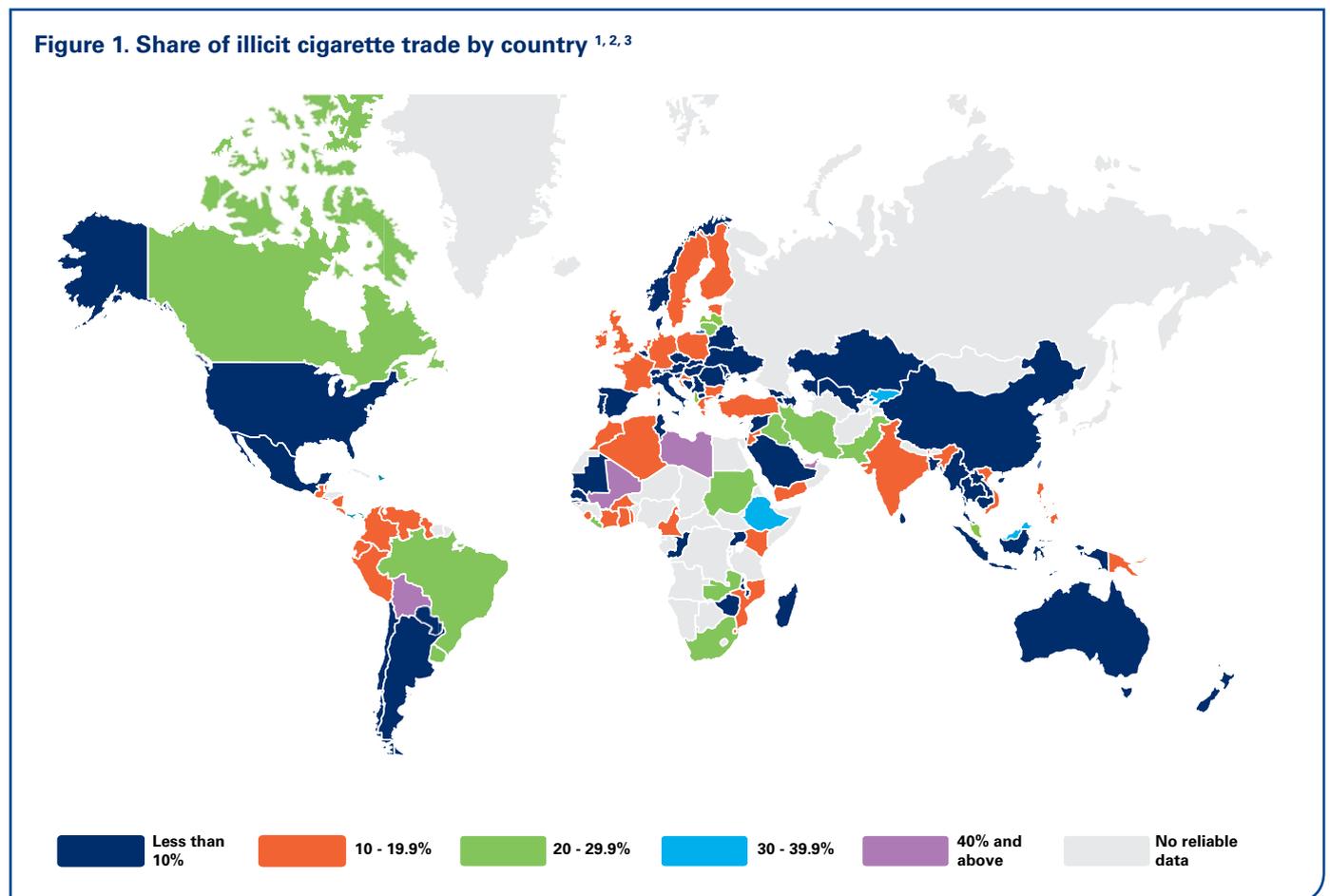
1. KPMG, Project Star 2012 Results, 16 April 2013
2. KPMG, Illicit tobacco in Australia 2013 half year report, October 2013
3. Latest available data

3.1. Definition and types of illicit tobacco products

Cigarettes, which account for over 90% by value of tobacco products sales, are the most illicitly traded form.[1] Various studies suggest that the illicit cigarette trade represents approximately 10%-12% of the total global cigarette market – although this varies by country.[1,2] Each year this translates to a loss of government revenues of US$40 to US$50 billion.[1,2]

The illicit trade in tobacco products is defined by the World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC) as "any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity".[3]

Figure 2. Types of tobacco products trade [1,2,4,5]

There are four categories of illicit tobacco products: contraband, counterfeit, illicit whites and unbranded tobacco.
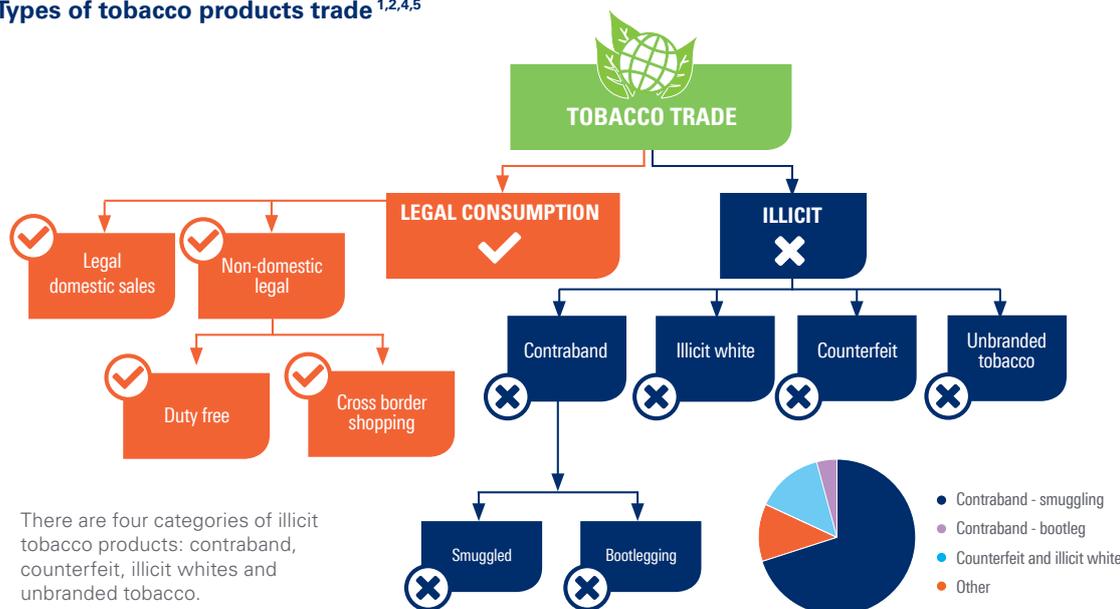
Definition

- **Legal consumption** comprises of legal domestic sales of manufactured cigarettes and loose tobacco.

- **Legal domestic sales** are sales of genuine domestic tobacco product through legitimate, domestic channels where all taxes and duties are paid.

- **Non-domestic legal products** are tobacco products that are brought from another country/state into the destination market legally by consumers. Non-domestic legal products are generally bought during cross border trips or/and at duty free shops.

- **Duty free sales** are purchases made at duty free shops where no state, local or provincial taxes, federal import duties or any other type of taxation is added to the cost of the item purchased. Duty free sales are generally subject to purchase volume restrictions.

- **Cross border shopping** is the purchase of tobacco products abroad by individuals because of lower taxes and the import of them for their own consumption.

- **Contraband cigarettes** are genuine products that have been bought in a low-tax country and which exceed legal border limits or are acquired without taxes for export purposes to be illegally resold (for financial profit) in a higher priced market. There are generally two types of contraband: bootlegging and wholesale smuggling/ organised crime.

- **Counterfeit cigarettes** are those which are illegally manufactured and sold by a party other than the original trademark owner.

- **Illicit whites** are cigarettes manufactured legitimately in one country for the sole purpose of being smuggled into and sold illegally in another country. In some cases illicit whites are produced in Free Trade Zones.

- **Unbranded tobacco** is generally sold as finely cut loose leaf tobacco and consumed in Roll Your Own (RYO) form or inserted into empty cigarette tubes. Unbranded tobacco generally carries no labelling or health warnings and may be grown illicitly without a licence or imported.

1. Euromonitor International, Passport: Illicit trade in tobacco products 2012, December 2013
2. International Tax and Investment Center, The Illicit Trade in Tobacco Products and How to Tackle It, Second Edition, 2013
3. World Health Organization (WHO), Framework Convention on Tobacco Control, 2003, accessed December 2013,
   http://whqlibdoc.who.int/publications/2003/9241591013.pdf
4. KPMG, Project Star 2012 Results, 16 April 2013
5. KPMG, Illicit tobacco in Australia 2013 half year report, October 2013

3.2. Causes of the illicit trade in tobacco products

The trade in illicit tobacco products is attractive to criminals and even opportunists for the following reasons:

- There is a large financial incentive to manufacture counterfeit cigarettes or to source tobacco in a lower-priced market, and then distribute and sell it in a higher-priced market;

- Sanctions or penalties if caught are perceived to be low;

- Current tobacco supply chain measures are not always adequately designed for effective product control; and

- Enforcement authorities face resource challenges.[1]

The trade in illicit tobacco products has not only grown but evolved significantly over the last few decades. It has changed in terms of nature and mix of products, as well as methods and routes of distribution. Historically, it was made up mainly of smuggled genuine tobacco products (contraband), whereas today it is much more a mix of contraband, counterfeit and increasingly illicit whites. Illicit whites are cigarette brands, produced at well known locations, which are only (or mainly) intended for the illegal market of another country. As manufacturers are often in accordance with local legislation, they can avoid legal action.

Illicit tobacco products are generally smuggled on a large scale by transnational criminal organisations, but also on a smaller scale by private individual bootleggers, and then sold to customers through local pubs or clubs, community centres, small retailers (alongside legitimate products), at local markets, by street peddlers, as well as new channels such as the internet. As enforcement authorities tighten their border and point of sale controls, tobacco smuggling and bootlegging routes and points of sale appear to be diversifying.

3.3. Efforts to eliminate illicit tobacco trade

Despite governments' enforcement efforts and increases in seizures (see Figure 3), the resources made available to those combating the trade in illicit tobacco products remains limited and the trade continues to grow. This growth not only undermines tobacco control policies, but also causes substantial losses to government revenues and contributes to the funding of transnational criminal activities. These issues encourage governments and international bodies such as the World Health Organization (WHO) to take further action.

The Protocol to Eliminate Illicit Trade in Tobacco Products, often referred to as the Protocol, which was negotiated under the Framework Convention on Tobacco Control (FCTC), is one of the efforts by the parties to the WHO to combat the trade in illicit tobacco products.

Figure 3. Worldwide seizures by type of product[2]
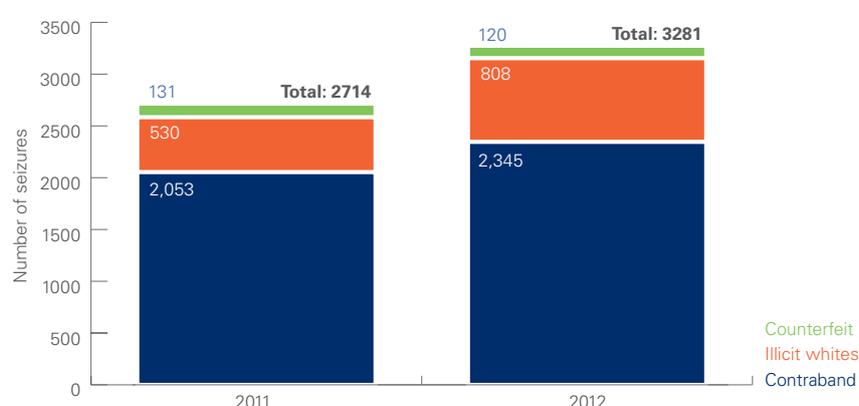
Number of seizures

2011: Contraband 2,053; Illicit whites 530; Counterfeit 131; **Total: 2714**
2012: Contraband 2,345; Illicit whites 808; Counterfeit 120; **Total: 3281**

Legend: Counterfeit, Illicit whites, Contraband

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1. *Chaudhry and Zimmerman, The Impact of Plain Packaging on the Illicit Trade in Tobacco Products , June 29, 2012*
2. *World Custom Organization (WCO), Illicit Trade Report, 2012*

4

An introduction to
track and trace

Track and trace systems developed from paper-based systems in the 1970s in the postal industry. Track and trace offers secure information on objects moving through supply chains and provides product integrity for brand owners, their customers, law enforcement agencies and even consumers.

4.1. Track and trace history

Tracking and tracing evolved in the postal and logistics sector to allow individual parcels to be moved with confidence within the companies concerned. Proprietary paper based systems were developed at first, which then evolved during the 1970s into automated electronic systems as a result of increasing international trade and the development of technology solutions. This enabled the automated capture and storage of large volumes of data.

Brand owners and manufacturers have turned to track and trace systems to protect their brands against increasingly sophisticated counterfeit products. The ability to 'track' products as they move forward through the supply chain as well as 'trace' the last known location of products are both valuable in addressing product diversion. Governments have also seen track and trace systems as a way to protect consumers from dangerous or sub-standard products, contaminated foods and counterfeit medicines.

4.2. What is track and trace?

The International Standards Organisation (ISO) defines track and trace as a "means of identifying every individual material good or lot(s) or batch in order

to know where it has been (track) and where it is (trace) in the supply chain".[1]

Track and trace systems provide information about a product or other object's progress through the supply chain from manufacturer, through wholesalers, distributors, logistics operators and finally to the end consumer. This information is useful in efficiently managing, controlling and securing legitimate supply chains. It also assists enforcement authorities in identifying who has handled suspect products and where these products entered the legitimate supply chain. Track and trace information is also able to identify where products have gone, enabling the effective recall of faulty products.

Tracking and tracing requires supply chain partners to record events related to objects under their control. For example manufacturers record the creation of products ('create event'), the packing of products into cases ('aggregation'), and their subsequent despatch to their customers ('despatch event'). Distributors then record the receipt of products ('receive event') and their onward delivery to their respective customers ('despatch event'). Information associated with these events, known as 'tracking events', is captured and entered into each companies' database, from which relevant information is uploaded into an event repository, as shown in Figure 4.

Common track and trace terminology:

- A **unique identifier** is an alpha numeric code which provides a unique identification for an object. It is analogous to a passport number for a person.

- **Event data** is the information associated with a **tracking event**. Common types of **tracking event** include product creation, aggregation of products into a carton or case, the despatch of products to a customer and the receipt of products from a manufacturer. **Event**

  data includes the unique identifiers of the objects involved, the time and location of the event and the event type.

- An **event repository** is a data base which stores event data.

- **EPCIS** (Electronic Product Code Information Service) is a GS1 standard for event repositories. It defines the data to be collected by a track and trace systems and how it should be entered and accessed.

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1. *International Standard, ISO 12931:2012 - Performance criteria for authentication solutions used to combat counterfeiting of material goods, First edition, June 2012*

Figure 4. Track and trace in the supply chain [1]

EVENT REPOSITORY

Database — Exchange shipping data → / ← Exchange receiving data — Database — Exchange shipping data → / ← Exchange receiving data — Database

Factory → DC → DC → DC → Store

Manufacturer	
EVENT	**DATA TO BE RECORDED**
Create event	Product UIDs, time and location
Aggregate event	Case UIDs, product UIDs, time and location
Despatch event	Case UIDs, ship to UID, ship from UID, time and location

Distributor	
EVENT	**DATA TO BE RECORDED**
Receive event	Case UIDs, ship to UID, ship from UID, time and location
Despatch event	Case UIDs, ship to UID, ship from UID, time and location

Retailer	
EVENT	**DATA TO BE RECORDED**
Receive event	Case UIDs, ship to UID, ship from UID, time and location
Disaggregate event	Case UIDs, product UIDs, time and location
Sale event	Product UIDs, time and location

Key UID = Unique Identifier
DC = Distribution Centre

1. FCTC, Conference of Parties – Intergovernmental Negotiating Body (INB) fourth session's provisional agenda item 3, FCTC/COP/INB-IT/4/INF.DOC./1 – Analysis of the available technology for unique markings in view of global track-and-trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products , 22 February 2010

The event repositories store the tracking event data and support a standard query method or interface, enabling supply chain partners or others with the required permission to retrieve information such as "who has handled this product?"; "when and where was this product manufactured?"; "do this company's records match those of its customers?".

Since the information is to be shared it is important that products and locations can be identified uniquely and unambiguously. This is achieved by giving each individual product or other supply chain object a globally unique identifier.

In addition, the precise meaning and format of the data to be collected must be agreed and understood.

For example, specifying whether the date and time should be in local time or UTC (GMT), or whether products should be recorded as despatched when the goods are ready to be loaded, or only after the truck has left the site.

Event data collection must be automated since the volume of products in most supply chains is too large to be collected manually. This is achieved by encoding the unique product identifier in a bar code or RFID tag, which can be quickly and accurately scanned and the relevant tracking event data recorded.

GS1 open standards are commonly used in track and trace. They can be divided into:

- Standards for identifying objects in the supply chain;

- Standards for capturing information about the objects; and

- Standards for sharing the information with business partners.

The 'identify' standards provide globally unique and unambiguous identifiers for a wide range of objects. The 'capture' standards define which bar codes and RFID tags can be used and the data they can contain. The 'share' standards enable secure and consistent information exchange through a range of standardised electronic messages and repositories.[1] These standards are summarised in Figure 5.

Figure 5. The GS1 standards framework[1]

The 'identify' standards provide globally unique and unambiguous identifiers for a wide range of objects

Company	**Product**	**Logisitics & Shipping**	**Location**	**Asset**	**Services**
• **Global Location Number (GLN)**	• **Global Trade Item Number (GTIN)** • **Serialised Global Trade Item Number (SGTIN)**	• **Serial Shipping Container Code (SSCC)** • **Global Shipment Identification Number (GSIN)** • **Global Indentification Number for Consignment (GINC)**	• **Global Location Number (GLN)**	• **Global Individual Asset Identifier (GIAI)** • **Global Returnable Asset Identifier (GRAI)**	• **Global Service Relation Number (GSRN)** • **Global Document Type Identifier (GDTI)** • **Global Coupon Number (GCN)**
Identifiers for manufacturers, distributors, transporters, subsidiaries, sales offices, bill to addresses etc.	Identifiers for each level of product pack including consumer packs, cartons/break packs, master cases etc.	Identifiers for groupings of products in transit for example on pallets, or in containers.	Identifiers for physical locations, including factories, warehouses, customs facilities, etc.	Identifiers for assets of all types, including production machinery, computers, vehicles, etc.	Identifiers for individual staff, customers, drivers and other service provider personnel. Also for documents such as licences and warranties.

The 'capture' standards define which bar codes and RFID tags can be used and the data they can contain

CAPTURE
GS1 Standards for Automatic Identification & Data Capture

GS1 Bar Codes

EAN/UPC	ITF-14	GS1 DataBar	GS1 DataMatrix	GS1 QR Code	GS1 Composite Barcode

GS1-128

EPC RFID

EPC HF Passive
EPC UHF Passive

The 'share' standards enable secure and consistent information exchange through a range of standardised electronic messages and repositories

SHARE
GS1 Standards for Automated Data Exchange

Master Data	**Transactional Data**	**Event Data**
• **Global Data Synchronisation Network (GDSN)**	• **eCom (EDI): EANCOM, GS1 XML Business Messages**	• **EPC Information Services (EPCIS)**

1. GS1, White paper: The need for global standards and solutions to combat counterfeiting, 2013

Figure 6. Track and trace or authentication[1]

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                    ┌─────────────────────────────┐
                    │   TRACK AND TRACE           │
                    │   OR AUTHENTICATION         │
                    └─────────────────────────────┘
         Is the object genuine?        Is the track and trace record complete?
        ┌──────────────────────┐          ┌──────────────────────┐
        │   AUTHENTICATION     │          │   TRACK AND TRACE    │
        └──────────────────────┘          └──────────────────────┘
    ┌─────────────┐  ┌─────────────┐   ┌─────────────┐  ┌─────────────┐
    │   OBJECT    │  │   OBJECT    │   │    TRACK    │  │    TRACE    │
    │  IDENTITY   │  │AUTHENTICATION│  └─────────────┘  └─────────────┘
    └─────────────┘  └─────────────┘
    Is the object    Does the object have the   Where is the object and   Where was the object
    identifier valid?  expected covert and/or    where is it headed?       (Locations & Custodians)
                     overt security features?
```

4.3. Track and trace versus authentication

As shown in Figure 6, track and trace systems are distinct from authentication systems, although they can work in combination to secure supply chains and prevent illicit trade. Authentication systems are designed to allow a product to be verified as 'real' and distinguish it from counterfeit goods, while track and track systems record a product's movement through the supply chain. Any gaps or inconsistencies in the record raise suspicion of illicit trade of some kind.

Track and trace systems are also distinct from tax verification systems which allow governments to tax, subsidise or simply verify that appropriate revenue has been paid. Whilst some markings (e.g. tax stamps) help to verify that tax has been paid and other systems allow government to monitor production and excise through 'digital tax verification', neither is intended to track and trace products.

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1. GS1, White paper: The need for global standards and solutions to combat counterfeiting, 2013

FCTC Protocol

To combat the increasing global illicit tobacco products trade the World Health Organisation (WHO) and its members, through the Framework Convention on Tobacco Control (FCTC), negotiated a Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol).

5.1. History of the Protocol

The WHO led the negotiation of a treaty in 2005 to reduce the global consumption of tobacco products by developing the Framework Convention on Tobacco Control (FCTC), which deals with measures to reduce both supply and demand for tobacco products.

The WHO FCTC entered into force on 27 February 2005[1] and under its auspices a draft 'Protocol to Eliminate Illicit Trade in Tobacco Products' was developed.[2] The Protocol was agreed on 12 November 2012 and will come into force following formal confirmation of its adoption by 40 countries (Parties).[3,4]

5.2. Objectives of the Protocol

The Protocol complements the FCTC's overall aims by introducing detailed measures to reduce the trade in illicit tobacco products given that it undermines efforts to reduce consumption. Demand for illicit tobacco products occurs most often because of its low price compared to legitimate tobacco products, ease of access and weak controls on its sale. The existence of illicit tobacco products works against both ambitions to control tobacco consumption and the key excise-based measures in the FCTC.

The Protocol's aims are explicit – to eliminate all forms of illicit trade in tobacco products by requiring Parties (i.e. countries) to take measures to control the supply chain of tobacco products and to cooperate internationally on a wide range of remediation measures.[5]

Article 8 aims to tackle illicit trade through the use of national and/ or regional track and trace systems and the establishment of a global information sharing focal point at the WHO Convention Secretariat. These obligations must be completed within a time window after the Protocol comes into force. This is five years for cigarettes and 'roll-your-own' tobacco, and ten years for 'other' tobacco products, including those for chewing and snuffing.[5]

Other means to ensure control of supply chains include licensing, due diligence, record keeping and security and preventive measures. Licensing requirements are imposed on the manufacture, import and export of tobacco products, manufacturing equipment as well as on sales to ensure that quantities sold correspond with the actual demand. Sales of tobacco products in free zones, international transit and duty free sales, the internet and other telecommunication modes will have to comply with the same comprehensive regulations as other sales.[5]

In imposing these obligations, there are some explicit and implied messages: that trade in illicit tobacco products is an international problem; that track and trace is part (but not the whole) of the solution; and that illicit tobacco products (uniquely amongst all the areas covered in the FCTC) are a large and complex enough issue to justify its own separate legal Protocol.

1. FCTC, History of the WHO Framework Convention on Tobacco Control, 2009, accessed December 2013, http://whqlibdoc.who.int/publications/2009/9789241563925_eng.pdf?ua=1
2. FCTC, WHO Framework Convention on Tobacco Control, 2003, accessed December 2013, http://www.who.int/fctc/text_download/en/index.html
3. United Nations, Treaty Collections, Chapter IX Health – Protocol to Eliminate Illicit Trade in Tobacco Products, Status as at 10 February 2012
4. WHO Framework Convention on Tobacco Control, Protocol - Ratification, accessed December 2013, http://www.who.int/fctc/protocol/ratification/en/
5. FCTC, Protocol to eliminate illicit trade in tobacco, 2013, accessed December 2013, http://apps.who.int/iris/bitstream/10665/80873/1/9789241505246_eng.pdf?ua=1

5.3. Status of the Protocol

The Protocol was open for signature between 10th January 2013 and 9th January 2014 and upon closing had been signed by 53 states and the European Union. Parties to the FCTC that did not sign the Protocol may still become Parties to the Protocol.[1]

On coming into force, it will be up to individual Parties to develop the solutions necessary to meet the requirements of the Protocol. However, following the completion of the Protocol, there has been little evidence of countries agreeing appropriate support mechanisms and guidance to help oversee the development of standards for tracking and tracing tobacco products. To bridge this gap a dedicated forum should be established to support the development of a set of international standards for the gathering and sharing of track and trace data.

5.4. FCTC Protocol tracking and tracing requirements

Article 8 of the Protocol requires Parties to establish a tracking and tracing system for tobacco products and to provide information which will be accessed through a global information sharing focal point located at the secretariat of the WHO FCTC.

Figure 7. Phases of Protocol development and implementation
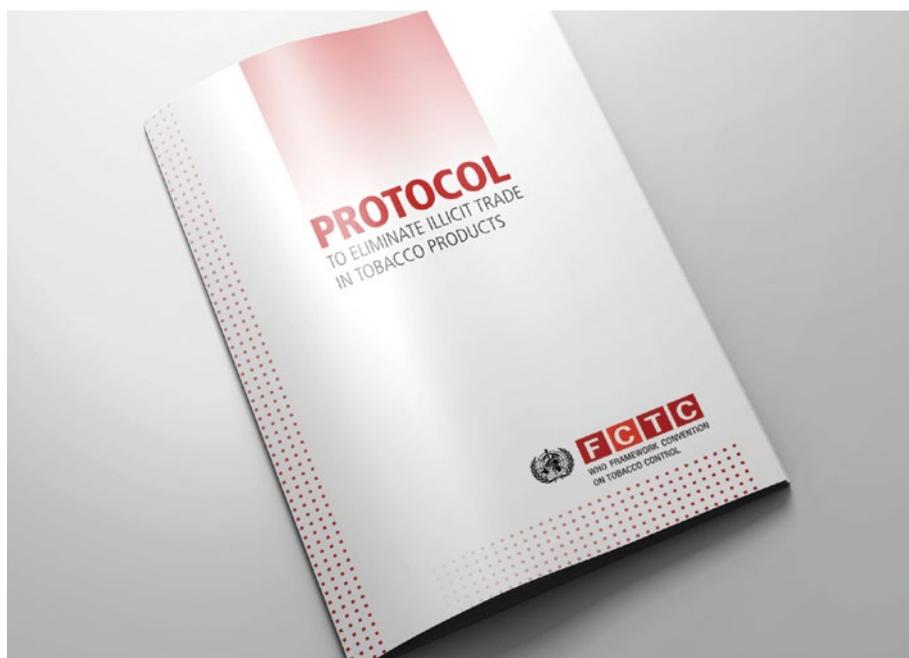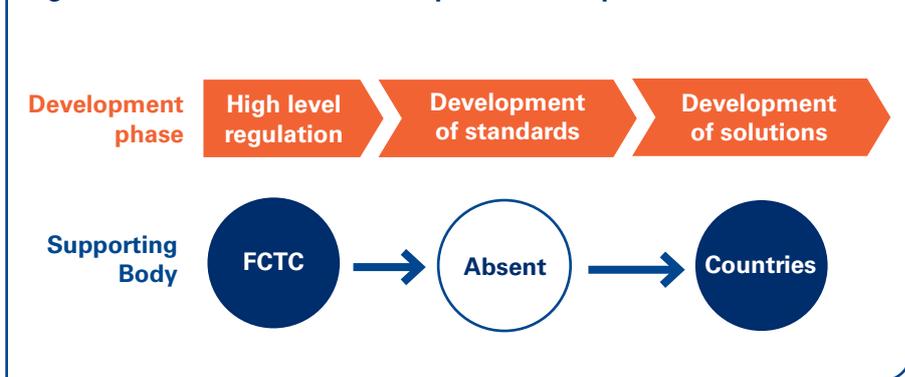
Development phase	High level regulation	Development of standards	Development of solutions

Supporting Body	FCTC	→	Absent	→	Countries

1. WHO Framework Convention on Tobacco Control, Protocol - Ratification, accessed December 2013, http://www.who.int/fctc/protocol/ratification/en/

> "...track and trace can help us in detecting where the diversion took place in the supply chain but only for genuine products...it will not help us so much on counterfeit products or illicit whites."
>
> Customs officer, Europe[1]

Article 8 requires unique, secure, and non-removable identification markings on all unit packets and packages of cigarettes and other tobacco products manufactured in or imported onto a country. These unique identification markings, when scanned by authorised authorities, would enable access directly or by means of a link to key information about the product, including details of manufacture, first customer, known subsequent purchasers and shipment (see Figure 8).

Parties to the Protocol will need to comply with these requirements within a period of five years for cigarettes and within a period of ten years for other tobacco products from the time the Protocol enters into force for that particular Party.[2]

Figure 8. FCTC Protocol Article 8 requirements[2]

Global information sharing focal point

National systems

Manufacturers and Distributors

Article 8.4 a-j

Unique, secure and non-removable identification markings enabling access to the following information:

- Date and location of manufacture
- Machine used to manufacture products
- Name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer
- Product description
- Identity of any known subsequent purchaser
- Manufacturing facility
- Production shift or time of manufacture
- Intended market of retail sale
- Warehousing and shipping
- Intended shipment route, shipment date and destination, point of departure and consignee

5.5. Expert reviews on track and trace

Prior to completion of the Protocol, a number of expert reviews and preliminary analyses of the feasibility of track and trace solutions were commissioned by the WHO FCTC. Although these reviews and analyses cover important considerations and recommendations, including key features of an effective track and trace system, not all of these considerations and recommendations are reflected in the final wording of the Protocol.

5.5.1. The creation of a track and trace regime

In one of the expert reviews and preliminary analysis documents, the WHO Expert Group highlights that "an international tracking and tracing regime would help prevent, detect and eliminate the illicit trade of genuine tobacco products, making it more difficult for smugglers. Such systems would need to be implemented at an international level, rather than each entity developing its own domestic system, in order to ensure that tracking and tracing across borders could be facilitated."[3]

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1. KPMG, Interview programme, January - February 2014
2. FCTC, Protocol to eliminate illicit trade in tobacco, 2013, accessed December 2013, http://apps.who.int/iris/bitstream/10665/80873/1/9789241505246_eng.pdf?ua=1
3. FCTC, Conference of Parties – Intergovernmental Negotiating Body (INB) third Session's provisional agenda item 4, FCTC/COP/INB-IT/3/INF.DOC./5 – Expert review on the feasibility of an international track and trace regime for tobacco products, 7 May 2009

> "...governments should be careful about exemptions [for SME's etc]...in our experience these have been exploited by organised crime groups.

Senior customs officer, Europe[1]

Based on the above, the purpose of an international track and trace regime is to facilitate investigations of tobacco products smuggling and bootlegging and to identify the potential points where they were diverted into illicit channels.

However, a tracking and tracing regime alone will not be able to eliminate all forms of smuggling and neither will it fully address the counterfeiting of products or illicit whites. The limitations of track and trace are also highlighted in our interviews with customs officers.

Thus, it may be important for governments to ensure stricter penalties for participation in the illicit tobacco products trade and to dedicate more resources to enforcement efforts.

One consideration in any track and trace system is the scope of the supply chain covered, together with the cost and operational impacts on the businesses within it. If exemptions are made for small or medium-sized businesses, the effectiveness of the track and trace regime will be compromised.

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1. KPMG, Interview programme, January - February 2014

> ❝ This is a global problem which requires a global solution…to be able to offer a global solution we need a standard that applies globally…
>
> Senior customs officer, Europe[1] ❞

5.5.2. The importance of open standards in developing a global track and trace regime

One of the expert review documents highlights the importance of the use of a global standard in developing a track and trace system. A global open standard is required to clearly define the basic requirements and procedures to be followed in designing and implementing a track and trace system.

This standard would allow for a common, cost-efficient, flexible approach to tracking and tracing, independent of the available technology.[2]

The importance of a global standard for tracking and tracing tobacco products is also highlighted by customs officers in our interviews.

In addition to the use of open standards, the WHO FCTC expert reviews emphasised that these standards should also not be "frozen" but open to adjustments at the international level to ensure the regime remains effective and up to date. This may require that the FCTC and other stakeholders revisit the global standard periodically and for a clear process to be in place for updating standards.

Definition of open standards in technology

- There are a number of definitions of open standards that are commonly used. The definition used within this report is that from the International Telecommunication Union (ITU), which encapsulates the most important elements of open standards.

- ITU defines open standards as standards made available to the general public which are developed (or approved) and maintained via a collaborative and consensus driven process. Open Standards facilitate interoperability and data exchange among different supply chain partners and are intended for widespread adoption.[3]

- ITU also suggests other desirable characteristics of open standards which include:

  - Reasonably balanced: to ensure the process is not dominated by any one interested party

  - No royalty: free for all to implement

  - Quality and level of detail: fully defined and stable, enabling systems to interoperate with each other

  - Publicly available: easily available for implementation and use, at a reasonable price

  - On-going support: maintained and supported over a long period of time

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1. KPMG, Interview programme, January - February 2014
2. IFOSSLR, Interoperability and open standards: The key to true openness and innovation, accessed January 2014, http://www.ifosslr.org/ifosslr/article/view/53/105
3. ITU, Definition of "Open Standards", accessed January 2014, http://www.itu.int/en/ITU-T/ipr/Pages/open.aspx

> **We are still at an early stage of track and trace development...technologies that are used for track and trace should evolve as everything around it changes.**
>
> Customs officer, Europe[1]

1. KPMG, Interview programme, January - February 2014

> "Getting systems to talk to each other is key...rapid and reliable information exchange is essential in law enforcement..."
>
> Customs officer, Europe[1]

Figure 9. Aggregation[2]

Aggregation Events

Pack → Carton → Shipping case → Pallet

Unique Identifier

The serial number, part of the SGTIN and SSCC, ensures that the same number is never assigned twice.
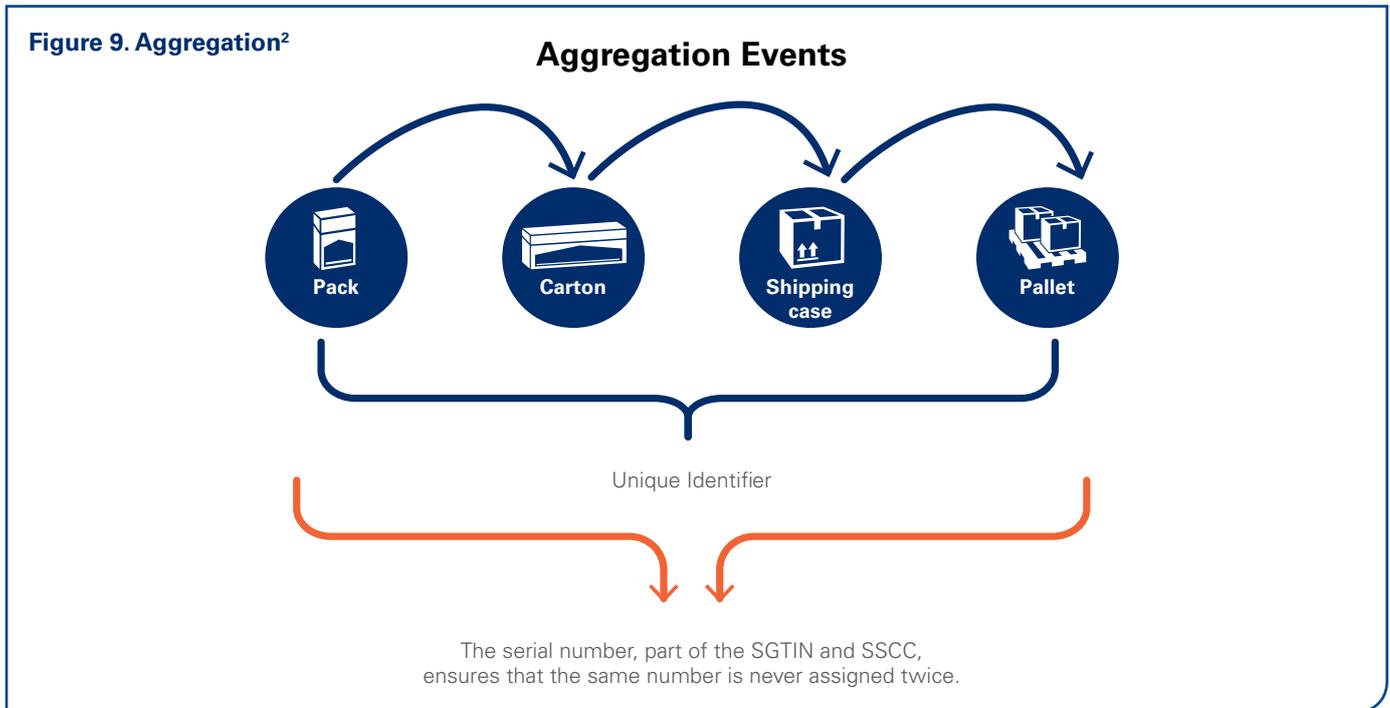
5.5.3. Features of an effective track and trace system

The WHO FCTC expert review identified the following as being essential elements of a track and trace system for tobacco products.[3]

5.5.3.1. Unique identification numbers

The track and trace identification numbering should be built on international standards. It should be unique for each individual unit of product (the smallest saleable unit) and non-predictable, so as to hinder counterfeiting.

It must also be human readable and in a format that can be extended so as to allow its continued use well into the future.

5.5.3.2. Marking technologies

The marking technology is the mechanism used to capture the data about the product. The choice of marking technology may vary depending on the capabilities of individual manufacturers but should conform to an open standard.

5.5.3.3. Aggregation of units

Aggregation establishes a parent-child relationship between the unique identification number of product units and sub units packed inside them (see Figure 9). In this way the unique identification number of an individual product pack is related to the unique identification number of the carton or case in which it is packaged. This will enable the movement of individual packs to be tracked and traced without the need to scan them individually, which would otherwise require the opening of their parent cartons/cases.

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1 KPMG, Interview programme, January - February 2014

2 IFOSSLR, Interoperability and open standards: The key to true openness and innovation, accessed January 2014, http://www.ifosslr.org/ifosslr/article/view/53/105

3 FCTC, Conference of Parties – Intergovernmental Negotiating Body (INB) fourth session's provisional agenda item 3, FCTC/COP/INB-IT/4/INF.DOC./1 – Analysis of the available technology for unique markings in view of global track-and-trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products , 22 February 2010

> **Ideally, we should be able to get information collected from track and trace systems directly…It would be beneficial for us if we can share data with other customs in other countries.**
>
> Customs officer, Europe[1]
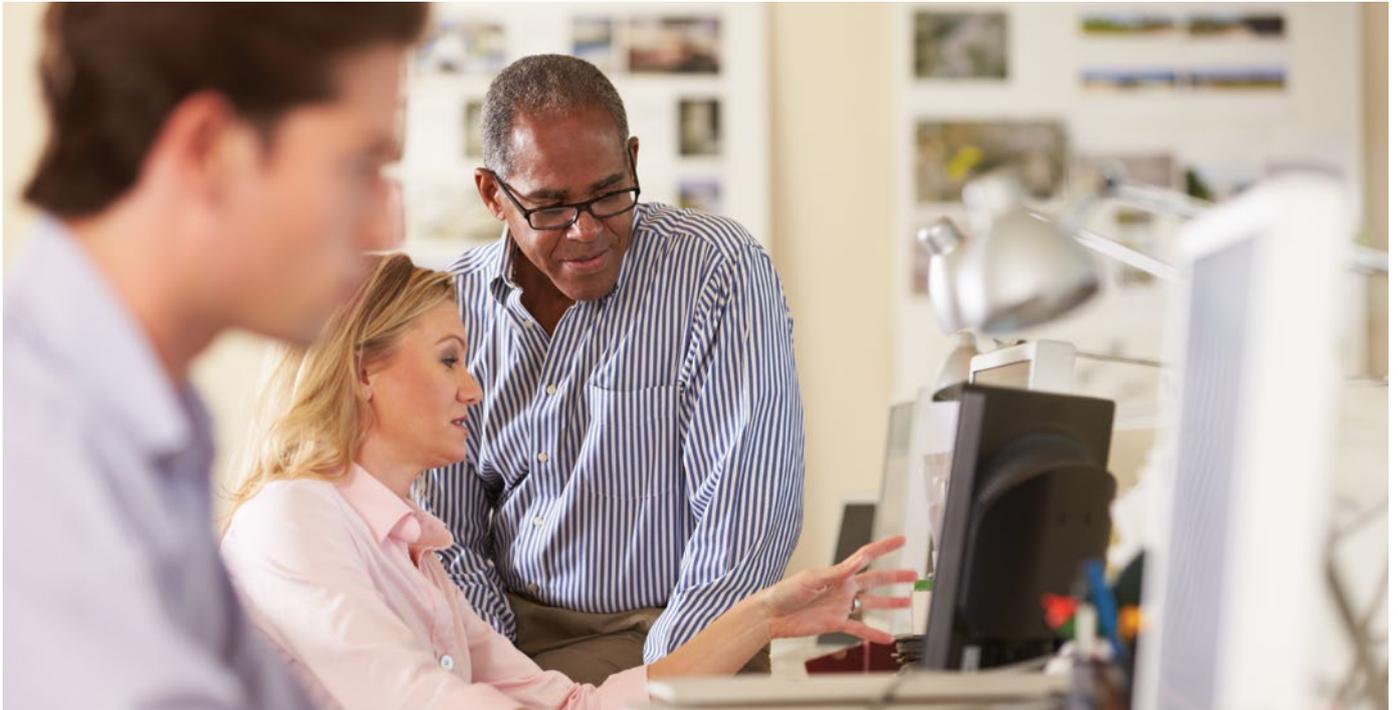
Aggregation can also establish a parent-child relationship between a logistic unit such as a pallet or container and any items within it. In this case the parent pallet or container is identified by a unique pallet identification number called a Serial Shipping Container Code (SSCC).

Aggregation requires any alterations to a parent unit, such as the removal of a case from a pallet or the taking of a sample for testing, to be recorded wherever it occurs throughout the supply chain.

5.5.3.4. Data capture

Certain practical pieces of information could be built into unique labels, such as product description, intended market of retail sale, date of manufacture and manufacturing facility, machine and production shift.

5.5.3.5. Supply chain events

Each shipper and receiver in the supply chain should be required to validate the units changing hands and record each of these supply chain events locally. Sharing and reviewing these events will help identify potential points of product diversion.

5.5.3.6. Data transfer

The exchange of this recorded data will take place at two levels. The first of these is between supply chain partners/manufacturers and national authorities. This data exchange could be implemented either as a data transfer into a national system, or alternatively through a national query engine which pulls data as needed directly from the manufacturers and supply chain partners' systems.

The second level at which data will be transferred is between national and international authorities, which would require national systems to support a standard query interface, such as the EPCIS standard. International cooperation in the design and operations of data transfer would be essential.

Our discussions with customs officers emphasise the importance of common data standards for effective information sharing from the track and trace regime.

6

Key learnings
from other industries

Track and trace has been deployed in many other industries to achieve different objectives. The lessons learnt from these sectors and what makes tracking and tracing effective can be brought together for wider application, including tobacco products.

6.1. Drawing lessons from other industries

A number of other industries have experienced supply chain leakage, like the tobacco industry, and were faced with the challenge of implementing a track and trace regime in response. Although the specific circumstances were different for each industry, the path taken to implement track and trace provides an insight into the challenges encountered and can help to develop a best practice approach for the implementation of track and trace in the tobacco industry.

The following case studies on track and trace implementations in the European and US pharmaceutical industries, timber and conflict minerals, as well as a case study on open standards in wi-fi, are analysed below. Additionally, the key implications for the tobacco industry are summarised.

EU PHARMACEUTICALS

6.2. Background

The pharmaceutical industry, similar to the tobacco industry, has been experiencing problems with the production and trade of illegal products. Falsified medicines are substantial and have become a growing worldwide illegal business.

6.2.1. Approach

In January 2013, Regulators in Europe adopted the European Falsified Medicines Directive (FMD) which aims to prevent falsified medicines from reaching patients by introducing harmonised, pan-European safety and control measures.[1]

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1 European Commission, EU Falsified Medicines - Directive 2011/62/EU, accessed February 2014,
http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

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> Track and trace serialisation is not particularly difficult in concept. However, to do it practically on production lines in 20-25 countries around the world, serialising 1-2 billion packs per year destined for a number of countries across 7,000-8,000 product is challenging. Doing this with one robust system and common way of working is hard enough. If you mix approaches it becomes very difficult.

An international/European pharmaceutical manufacturer[1]

The European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents the European patent medicines industry, worked closely with regulators to create the directive. Initially, EFPIA members responded to the legislation on their own. However, they soon realised that the support of other stakeholders, such as pharmacists, was vital for the success of any solution. Accordingly, EFPIA invited other industry groups to form the European Stakeholder Model (ESM) to cooperate in developing a response to the Directive.[2]

In developing its approach, EFPIA worked with regulators to agree that the overriding objective of the FMD was patient safety and that all other issues such as anti-counterfeit and reimbursement were relatively unimportant. This agreement was helpful in resolving differences within the EFPIA industry group.

One principle agreed early on was that a single central database was not a practical approach to protecting against illicit medicines. This was partly due to legislation in some countries which requires that data is held within their borders and under their control, but also because different countries were likely to require the system to do different things. Any solution therefore had to enable national governments to manage their own database and data.

The EFPIA approach is to individually identify products with a random unique identifier and to confirm that the identifier is valid before dispensing the product to the patient. This authentication approach removed the requirement for full track and trace through the supply chain.

The EFPIA solution is based on a European central hub connected to a series of national or regional data repositories. All manufacturers and re-packagers are required to enter their information into the central hub. The data is then passed on to the relevant regional or national track and trace repositories which serve as the verification platforms to check the validity of the product identifier.

EFPIA also plans to develop a basic national application or a base system – to be governed nationally, but managed and operated on an EU level – for those countries that do not want to build their own national repositories. For this system to work, standards for product identification and machine readable data carriers, such as bar codes, were identified as an essential requirement and the decision taken to base the system on the open standards provided by GS1.

EFPIA created a successful pilot in Sweden to prove the feasibility of this approach. Thereafter, EFPIA and the European Association of Euro-Pharmaceutical Companies (EAEPC), The European Association of Pharmaceutical Full-line Wholesalers (GIRP) and the Pharmaceutical Group of the European Union (PGEU) issued a joint position paper on their approach to the FMD Directive and then moved on to specification and implementation.

The EFPIA approach is based on open standards. However, some countries had already developed their own national systems in advance of the EFPIA initiative. For example, Germany had already created a 'closed' national system called SecurePharma. EFPIA is working to include these systems and GS1 has worked with EFPIA to facilitate the extension of GS1 standards to enable migration with the ultimate aim of a solution fully based on open standards.

> **"** All parties - governments, customs, trade bodies, manufacturers - need to cooperate...I don't think track and trace can be implemented effectively without cooperation of all parties. **"**
>
> Customs officer, Europe [1]

EU PHARMACEUTICALS

6.2.2. Key learnings

- EFPIA uses an approach based on the open standards provided by GS1 to enable flexibility at the country level and at the same time ensure interoperability at the European level.

- Industry associations such as EFPIA have helped with and even taken the lead in the development and establishment of an open standard.

- A track and trace regime is a complex construct that requires collaboration between many parties, including industry players. EFPIA does not work alone – it not only collaborates with governments but also with other industry organisations. Together, they established the European Stakeholder Model (ESM) to build an EU-wide coding, serialisation and verification system.

- A track and trace regime is more effective if the system adopted can operate with existing business processes and IT infrastructure. By reducing the number of systems that supply chain participants have to use, the reliability of data is enhanced and the cost of adoption reduced.

- Some countries may require assistance in adopting an open standard and implementing a track and trace system. Industry associations such as EFPIA are able to provide support and assistance where necessary.

- Track and trace systems have to be flexible and adjustable to the requirements and needs of each country.

6.2.3. Implications for tobacco industry

- Currently, there are no globally agreed open standards for tracking and tracing tobacco products as part of the FCTC Protocol. National governments should clearly encourage the use of open standards, to drive up adoption and drive down cost.

- It will be necessary to establish a dedicated forum to take the lead in the development and establishment of an open standard for tracking and tracing tobacco products. This forum can also assist governments in interpreting the FCTC requirements at a country level and in implementing track and trace systems when required.

- Cooperation among all relevant stakeholders is required to agree the standards necessary for an efficient international track and track regime. Governments, including customs officers, industry associations, manufacturers, distributors and retailers must cooperate with each other in implementing the tobacco track and trace regime.

- Governments should adopt systems that can be integrated with existing business processes and IT infrastructure. This will reduce the number of systems that supply chain participants have to use, increase the reliability of data and reduce the cost of adoption.

- Governments have to ensure that the adopted track and trace system is flexible enough so that it can be adjusted to their specific requirements and cope with future technological developments.

> "In my opinion, it will be very difficult not to involve industry players as they will need to provide us with data and fund this – we need their cooperation…
>
> Customs officer, Europe [1]

US PHARMACEUTICALS

6.3. Background[1]

The pharmaceutical industry in the US has until recently depended on a state by state approach to secure supply chains and tackle the growth in production and trade of falsified medicines. However, allowing individual states to create their own inconsistent approaches was seen as likely to fail due to the limited capability to share information and the lack of interoperability between state's systems. The US Government enacted the Drug Quality and Security Act (DQSA) in November 2013 to create a single federal approach to secure the US pharmaceutical supply chain.

6.3.1. Approach

The Act aims to establish national standards to improve the security of the pharmaceutical supply chain and to drive the industry's response. It gives the Food and Drug Administration (FDA) one year to publish guidance containing standards and guidelines for companies in the supply chain to exchange transaction information.

In developing these standards the FDA must consult with other appropriate federal officials, manufacturers, re-packagers, wholesalers, distributors, dispensers and other pharmaceutical supply chain stakeholders.

The guidelines that the FDA will publish must comply with a form and format developed by a widely recognised international standards development organisation, although no specific organisation has been identified.

A major issue to ensure effectiveness of the track and trace regime will be getting pharmacists, of which there are thousands in the US, trained and equipped with the correct readers and internet access.

6.3.2. Key learnings

- A state by state approach failed to create an effective track and trace regime. A common approach complying with widely recognised international standards would have been preferable.

- To establish an efficient track and trace regime, the cooperation of different supply chain stakeholders is needed. This was seen as so important that within the Act the FDA was given a direction to consult with other appropriate federal officials, manufacturers, re-packagers, wholesalers, distributors, dispensers and other pharmaceutical supply chain stakeholders.

- The application of track and trace is not simple. The availability of equipment, training and other support is required to ensure its effectiveness.

6.3.3. Implications for the tobacco industry

- An international track and trace regime for tobacco products can only be effective if each national system is interoperable with others and can exchange data efficiently across borders. Therefore, in adopting a track and trace regime, it is preferable for governments to encourage the use of a common approach complying with widely recognised international standards.

- Cooperation among all relevant stakeholders is required to develop an efficient track and track regime for tobacco products. Governments should encourage this.

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1 KPMG, Interview programme, January - February 2014
2 FDA , Drug Supply Chain Security Act - Title II of the Drug Quality and Security Act of 2013, accessed February 2014, http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm

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TIMBER

6.4. Background

There has been growing pressure in recent years for companies to track the origins of the timber they use to prove it has been legally and sustainably sourced. Pressure from governments, along with EU timber regulation[2] and the US Lacey Act[3], means that companies which use timber in their products are increasingly turning to track and trace systems to prove their compliance with laws regarding sourcing timber.

6.4.1. Approach

There are a number of companies on the market offering timber tracking solutions, which vary in sophistication from paper based tracking methods to full enterprise resource planning (ERP) based electronic systems. Current trends and developments are pushing the market towards full electronic systems. However, although many pilot implementations have taken place, the cost/benefit balance is not always achieved so large scale uptake of electronic systems has not happened. Currently funding for research is reliant on public money, rather than the forest or factory owners paying for the systems themselves.

The systems used for identifying and tracking timber vary widely, from batch monitoring, to paint marking or tagging, to using RFID tags or bar codes or 'DNA' tracking.

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1. KPMG, Interview programme, January - February 2014
2. EURO-Lex, Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market Text with EEA relevance, accessed January 2014, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0995:EN:NOT
3. Office of Law Enforcement , Lacey Act, accessed January 2014, http://www.fws.gov/le/pdffiles/Lacey.pdf

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> "The ideal solution to tracking timber products would involve an industry wide consensus, where systems of different service providers could adapt to a baseline standard. This would more readily allow for the facilitation of data exchange between service and timber tracking software providers."

Sustainable timber track and trace expert[1]

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1 Felix Seidel, Review of Electronic and Semi⬚Electronic Timber Tracking Technologies and Case Studies, accessed January 2014, http://www.itto.int/files/user/pdf/Meeting%20related%20documents/Timber%20Tracking%20Review.pdf

The systems carry a range of information such as product size, weight, cost, species, date and location when the timber was felled.

There has currently been no attempt to produce industry-wide standards to track and trace timber, leading to many disjointed proprietary providers providing different systems and differing information sets.

Industry experts believe that the timber industry could benefit from the development of industry-wide open standards. However, evidence suggests this is unlikely due to the vested commercial interests of the many private providers of systems in this sector.

6.4.2. Key learnings

- The unavailability of industry-wide standards to track and trace timber has led to the proliferation of proprietary systems from providers which cannot adapt to a baseline standard or facilitate data exchange.

- Often, proprietary providers do not support the use of open standards due to their vested commercial interests.

6.4.3. Implications for the tobacco industry

As previously highlighted in other case studies, the experience in the timber industry also shows that an industry-wide standard for tracking and tracing tobacco products would support success and that the best way to achieve this on a global scale is through using open standards rather than proprietary solutions.

CONFLICT MINERALS

6.5. Background

The long-standing link of minerals with conflict in the Democratic Republic of Congo (DRC) has led to an increasing need for transparency in the supply chain of minerals sourced from this area. In July 2010, the US government introduced the Dodd-Frank Wall Street Reform Act[1], part of which requires companies regulated by the US Securities and Exchange Commission (SEC) to ensure that the raw materials used in their products are not linked to the conflict in the DRC or the surrounding Great Lakes Region. This means that companies should be able to trace their mineral supply chains for tin, tungsten and tantalum, which are all mined in this area.

6.5.1. Approach

Part of the current solution for tin, tungsten and tantalum has been implemented by ITRI, an organisation representing the tin industry. This solution, iTSCi (ITRI Tin Supply Chain Initiative)[2], tracks bags of minerals from the mine, through any processors and traders, to the smelter and provides the necessary information for companies to conform to the Organisation for Economic Co-operation and Development (OECD) Due Diligence Guidance.

The OECD Due Diligence Guidance for responsible supply chains of minerals provides detailed recommendations for companies that are potentially sourcing minerals or metals from conflict-affected and high-risk areas with "a five step, risk based due diligence framework"

as a tool to develop transparent mineral supply chains and avoid contributing to conflict through their activities. The guidance is also intended to assist companies to meet requirements under national laws such as Dodd-Frank.

iTSCi is a member-based programme, so any upstream company (e.g. mining and extraction companies) of any size can join. It is funded by downstream companies (e.g. product manufacturers) who can join as associate members. iTSCi is currently in operation in eastern DRC and in implementation phase in southern DRC and Rwanda.

iTSCi works through adding bar-coded tags with unique serial numbers to bags of minerals. These tags can be added at two places: firstly at the mine, where the tag is added on extraction, or secondly during processing, where a second tag is added. Alongside these tags, log books at each site record detailed information about the dates, mine, processor, exporter, route taken, price and weight, as well as the tag numbers. This data is fed into the iTSCi database, which is hosted on a server in Canada and can be accessed online from anywhere in the world. This gives the required chain of custody information to US companies to report on their Dodd-Frank requirements.

iTSCi has become the dominant provider in this international field as it has so far been the only

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1. US Securities and Exchange Commission - One Hundred Eleventh Congress of the United States of America, An Act - H. R. 4173, accessed January 2014, http://www.sec.gov/about/laws/wallstreetreform-cpa.pdf
2. ITRI website, accessed January 2014, www.itri.co.uk

> **It would be great to have one standard. The problem is that getting from here to there is complicated and so I think we [NGOs and end users] are in favour of multiple competing systems that follow certain key guidelines and standards.**
>
> NGO working in this area[1]

solution available. New providers are now entering the market and there are worries about compatibility of several different systems from upstream companies, who want an easy system to use, and NGOs and regulators, who want full traceability. The iTSCi database is not transparent in its reports so it would be difficult for another provider to feed in to this.

6.5.2. Key learnings

- Clear guidelines and standards are required to enable a number of providers to supply track and trace solutions.

- As long as such guidelines and standards exist, it is favourable for an industry to have a number of competing providers rather than one dominant player in the market. As the conflict mineral case study shows, over reliance on one provider will likely result in less effective track and trace.

6.5.3. Implications for the tobacco industry

- Once again, it has been shown that an open standard and the resulting competition are beneficial to the success of a track and trace solution. Therefore, governments need to encourage competition in the market by enabling multiple providers to offer track and trace solutions as long as they comply with agreed open standards.

- As highlighted previously, it is advisable to develop clear guidelines and standards for the tobacco industry. A new or a currently established forum can help develop these based on the FCTC Protocol requirements.

Wi-Fi TECHNOLOGY

6.6. Background

In 1985 the Federal Communications Commission (FCC), America's telecoms regulator, opened several bands of wireless spectrum, allowing them to be used without the need of a government licence. This encouraged a number of vendors of wireless equipment for local area networks (LANs) to develop their own proprietary equipment which operated in the unlicensed bands. However, equipment from one vendor could not talk to equipment from another and the products had relatively little success.

6.6.1. Solution

Several vendors realised that with a common wireless standard, buyers would be more likely to adopt the technology as they were not 'locked in' to a particular vendor's products.

NCR Corporation initiated a process for developing industry standards through the Institute of Electrical and Electronics Engineers (IEEE), which in 1997 resulted in the standard known as IEEE 802.11.

Products based on this standard, which eventually became known as Wi-Fi, soon started to appear.

In July 1999, Apple introduced Wi-Fi as an option on its new iBook computers. Other computer manufacturers followed suit and the market took off, as shown in Figure 10.

Subsequently improved versions of the standard have been developed, allowing for greater speeds, while product costs have fallen.

Figure 10. Untethered growth[1]
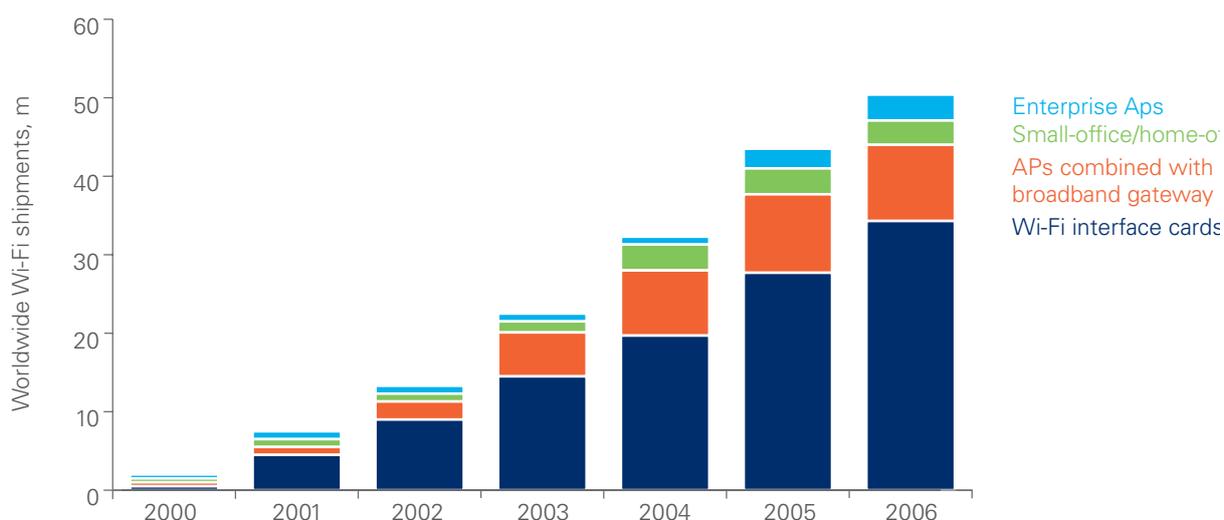
Legend:
- Enterprise Aps
- Small-office/home-o...
- APs combined with broadband gateway
- Wi-Fi interface cards

Y-axis: Worldwide Wi-Fi shipments, m
X-axis: 2000, 2001, 2002, 2003, 2004, 2005, 2006

1. Dell'Oro Group, quoted in The Economist, A brief history of Wi-Fi, accessed December 2013, http://www.economist.com/node/2724397

> **"** This is a global problem. The effectiveness of track and trace implementation will depend on whether or not all countries are committed to do this. **"**
>
> Customs officer, Europe[1]

Prior to the agreement on the 802.11 standard, wireless connection hardware, known as access points, supported less than 2 Mb/s and sold for around $1,500. Today, access points supporting 54Mb/s can be bought for less than $50.

6.6.2. Key learnings

- Common standards facilitate different providers entering the market and offering the required technology.

- With a number of providers offering a solution, it is likely that the price charged for the solution will decrease. The lower the price, the higher the likely adoption of that solution or technology becomes.

- In some cases, support from the industry or certain stakeholders - in this case Apple - may foster successful adoption of a technology or solution.
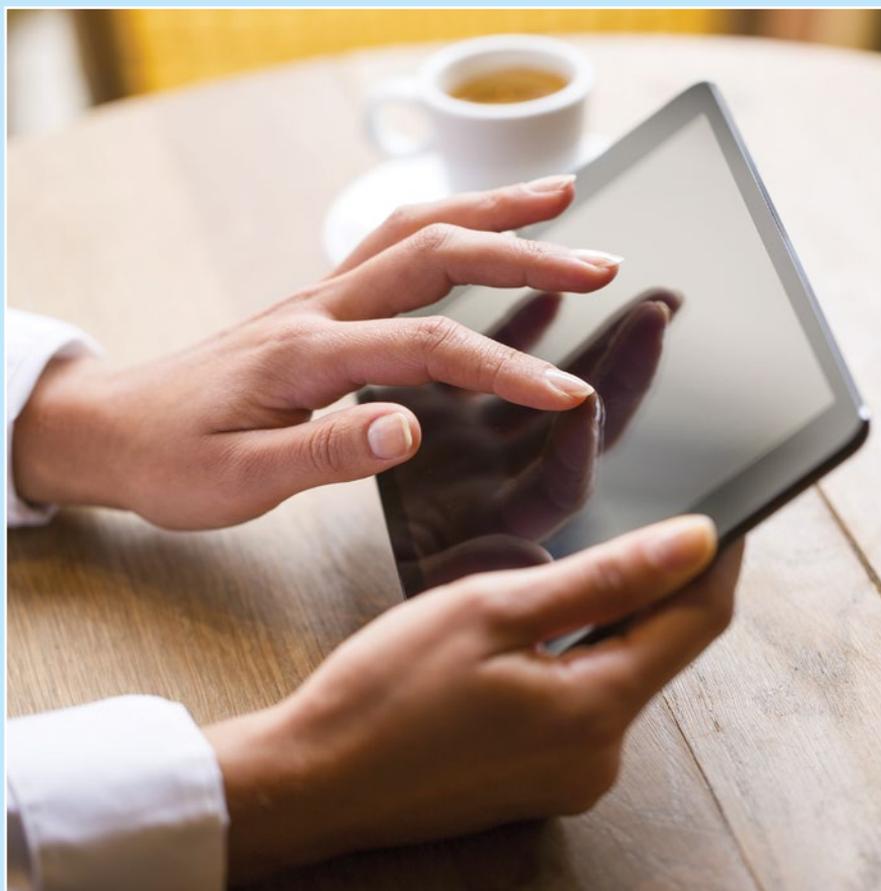
6.6.3. Implications for the tobacco industry

An open standard increases competition which in turn reduces the cost of the solution, encouraging widespread adoption. This is relevant for ensuring the Protocol is as effective as possible – not least in less developed countries where the costs of implementation could act as a barrier to implementing track and trace.

> **Illicit trade in tobacco products is not a single country problem, we need international cooperation to ensure track and trace works...**
>
> Customs officer, Europe[1]

6.7. Key recommendations for the tobacco industry

The following recommendations are intended to support the adoption and implementation of an effective track and trace regime for tobacco products.

6.7.1. Open standards are key to implementing an effective track and trace regime

A number of case studies indicate the importance of open standards. Track and trace regimes are much more likely to be effective if open standards are adopted as they enable each national system to be interoperable and to exchange data efficiently.

The use of open standards is likely to result in the following:

- Wider adoption which in turn improves the penetration of the system;

- Lower implementation costs by allowing countries to choose technologies at will, as long as they comply with standards; and

- Ability to update track and trace systems as technology advances.

6.7.2. Competition amongst providers must be enabled and encouraged

The conflict mineral case study highlights the benefit of competition amongst providers. A single provider or one dominant provider in the market can cause difficulties for those within the supply chain due to their market dominance which could work against cost effective track and trace.

Governments need to encourage competition in the market by enabling multiple providers to offer track and trace solutions, as long as they comply with the agreed open standards.

6.7.3. Track and trace systems should be integrated with existing business processes and IT infrastructure

The European pharmaceutical case study shows that a track and trace regime is more effective if the system adopted can operate using existing business processes and IT infrastructure. This will reduce the number of systems that supply chain participants have to use, increase the reliability of data and reduce the cost of adoption.

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1. *KPMG, Interview programme, January - February 2014*

6.7.4. Pan-regional/global cooperation is essential

The US pharmaceutical case study shows that it is difficult to create an effective track and trace regime with a state by state approach. Pan-regional cooperation is an important factor for a track and trace regime to succeed.

The trade in illicit tobacco products is a global problem which requires a global solution. International cooperation is required to develop a sustainable and effective track and trace regime. This will only be effective if each national system is interoperable and can exchange data efficiently.

6.7.5. Effective track and trace requires collaboration between a number of stakeholders, ideally via a dedicated forum

As well as cooperation between different countries, the involvement of all supply chain stakeholders on a national and international level is required to develop an effective track and trace system for tobacco products. as shown in the European pharmaceutical case study. Governments, including customs officers, industry associations, manufacturers, distributors and retailers should cooperate with each other in implementing a tobacco track and trace regime.

In the European pharmaceutical case study, an industry association (EFPIA) helped in the development

and the establishment of an open standard in track and trace. For the tobacco industry, it will be necessary to establish a dedicated forum to lead the development and establishment of an open standard. This forum could also assist governments in interpreting FCTC requirements at a country level and potentially implementing a national track and trace system if required.

In order to assist countries in meeting the requirements of the FMD Directive, EFPIA are proposing developing a base system governed nationally but managed and operated on an EU level. A similar approach could assist countries in meeting the FCTC Protocol requirements, especially those with limited resources.

7

Track and trace
solutions

Track and trace solutions, which are a part of the anti-counterfeiting and brand integrity market, are broadly served by two groups of provider – security printing companies and IT/data processing companies both of which have different backgrounds.

7.1. Track and trace solutions overview

Track and trace solution providers sit within the anti-counterfeiting and brand integrity market.

This market is highly fragmented and complex, covering different technologies and industries.

The tobacco products anti-counterfeiting and brand integrity market accounts for approximately 3.5% of the overall market and is expected to grow by approximately 15% per annum until 2024.

7.2. Track and trace providers

The provider landscape features two broad groups – security printing companies and IT/data processing companies. These two groups have different backgrounds and heritages that impact their solutions and approaches to track and trace (see Figure 12).

7.2.1. Security printing companies

Security printing companies primarily offer product authentication solutions but have expanded their service offerings to include track and trace in recent years.

Their key strengths are in product authentication and printing technologies using ink and dyes, and overt and covert technologies such as holograms, watermarks and taggants.

They have developed proprietary authentication technologies to enhance their competitiveness in the market.

A number of these companies provide authentication products (e.g. tax stamps), which can be complementary to track and trace systems. By offering tax, authentication and track and trace functions, these providers can potentially offer traceability services which are integrated into existing business and IT processes.

This appears to be one of the reasons why they recently expanded their services to include track and trace.

Currently, deployments of their technologies have tended to be in individual businesses and interoperability with other systems has been infrequent.

Due to their heritage and background, security printing companies tend to believe that proprietary technologies are important and protect their competitiveness in the market. It is likely that they will continue to deploy proprietary technology unless they are requested to comply with open standards.

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1. Visiongain, Anti-counterfeit packaging technologies market forecast 2014-2024 and future prospects for leading companies, January 2014

> "This is still a nascent market place, vendors are competitive and our differentiation is around our solutions being provided. When standards come into play, it's harder to compete and differentiate your offer against the standard."
>
> Security printing provider[1]

Figure 12. Types of providers[2]

Solutions

PRODUCT AUTHENTICATION	PRODUCT TRACK AND TRACE

Types of provider

SECURITY PRINTING COMPANIES

IT/DATA PROCESSING COMPANIES

Product technologies

INKS AND DYES	HOLOGRAMS	BAR CODES
WATERMARKS	TAGGANTS	RFID

Applications

BANK NOTES	TAX STAMPS	FMCG	INDUSTRIAL MARKETS
IDS, CARDS AND OTHER SECURE DOCUMENTS	PHARMACEUTICALS	FOOD	OTHER

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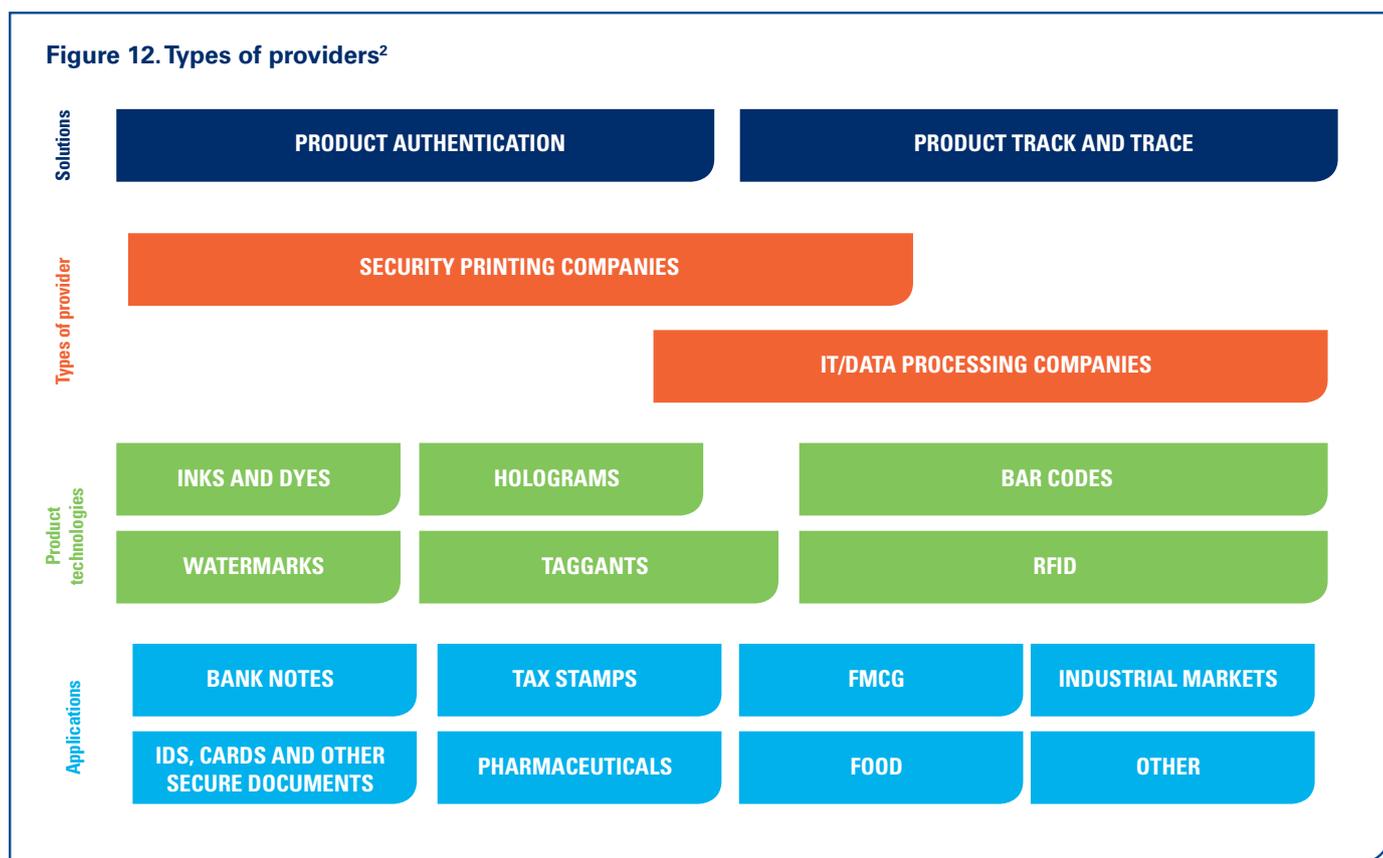
1. KPMG, Interview programme, January - February 2014
2. KPMG analysis of Top 25 suppliers – anti-counterfeiting and product security technologies, 2013 and Visiongain, Anti-counterfeit packaging technologies market forecast 2014-2024 and future prospects for leading companies, January 2014

Figure 13. Comparisons of track and trace features by provider group[1]

PROVIDER GROUP

TRACK AND TRACE FEATURE	SECURITY PRINTING COMPANIES	IT/DATA PROCESSING COMPANIES
Unique Identification Numbers The Protocol refers to unique identification markings, which must be human readable and so numbers are likely to form a part in most deployments.	A range of numbering systems has been deployed – ranging from low simple serial numbers through to algorithm based high volume deployments. Some deployment of standards in numbering.	Systems tend to operate across larger deployments with capacity for larger numbers of unique ID's. GTIN standards often deployed in the structure of the unique ID.
	In effective tracking and tracing systems for controlling illicit trade the identifier should be both random and unique. The latter ensures accurate tracing of seized product and reduces the risk of duplication becoming a loophole exploited by criminals. A diverse patchwork of systems increases this risk	
Marking technologies Key technologies for embedding the unique identification markings at unit and aggregated level.	RFID tags, bar codes and combinations of the two used. Sometimes supplemented with forensic technology like material footprint and special taggants in product and packaging.	RFID tags, bar codes and combinations of the two used. Forensic technologies can be provided by third parties.
Creation of parent–child relationships (aggregation) To facilitate practical unit level tracking, aggregation will be necessary.	Aggregation and disaggregation are sometimes available depending on the deployment.	Aggregation and disaggregation commonly a feature based on tracking at case, pallet or container level.
Data to be captured The minimum data requirements for Protocol -compliant Track and Trace systems are detailed in the Protocol at 8.4.1[(a)].	Greater reliance on proprietary provision and ongoing control of the Track and Trace systems which may hinder cross-border/regional deployment	Use of outsourced providers and willingness to work with them to operate systems at 'arms length' from software providers
Recording of supply chain events Number and nature of recording events should be designed with national illicit tobacco priorities in mind, but is not prescribed in Protocol.	Ranges of events are captured depending on application.	Ranges of events are captured depending on application.
Data capture, transfer and exchange Addresses the need for data to be exchangeable and the ability for global information-sharing. Focus will be required on response times for high data volumes.	Different deployments operate with differing data collection requirements. Some use of standards when client requests it, but not widespread.	Many systems deploy standards such as EPCIS and GS1 bar-codes. Events captured depend on the deployment concerned, but systems are commonly designed to interface with multiple applications. Ability to allow international interrogation/exchange materially more effective
Overall Taking into account key features of effective tracking and tracing and the requirements described in the Protocol.	**Some security based systems may meet compliance requirements of the Protocol. However, their capabilities are weaker in terms of data capture, aggregation, transfer and exchange.**	**The wider spread use of standards within systems supports more effective management of high volumes of data. Ability to work with outsourced providers and aggregation capabilities ensures better fit with effective Protocol implementation.**

KEY: ● Very high   ◕ Very high   ◑ Medium   ◔ Low   ○ Very low

NOTE: (a) Data requirements in the Protocol are: (a) date and location of manufacture; (b) manufacturing facility; (c) machine used to manufacture tobacco products; (d) production shift or time of manufacture; (e) the name, invoice, order number and payment records of the first customer who is not affiliated with the manufacturer; (f) the intended market of retail sale; (g) product description; (h) any warehousing and shipping; (i) the identity of any known subsequent purchaser; and (j) the intended shipment route, the shipment date, shipment destination, point of departure and consignee

1. KPMG analysis

> "There is no willingness to move to a common standard unless it is defined by the industry. The biggest danger is imposing a solution on an industry without making the players agree on the standard and information to be used.
>
> Security printing provider[1]

7.2.3. IT/data processing companies

A second group of providers come from an IT/data processing background, which focuses more on data collection and logistics capabilities. These providers tend to work on track and trace technology solutions in relation to supply chain management and logistics. They need to support supply chains which cut across different companies' systems, such as enterprise resource planning (ERP) or warehouse management systems (WMS).

The key strengths of IT/data processing companies lie in capturing and dealing with a large amount of data from various stakeholders in different stages of the supply chain. Because of the large amount of data they need to capture and share with various stakeholders, who often have different systems, these providers tend to be more supportive of standards. They are likely to have

already adopted standards that are used in other industries (e.g. GS1 EPCIS) and mostly have experience with commercial models that encourage open standards.

7.2.4. Suitability of providers to meet FCTC requirements

As highlighted in section 5, there are a number key requirements laid out in the FCTC Protocol which have to be met to ensure that tobacco products can be effectively tracked and traced. The following table summarises solutions currently offered by the two provider groups against these key requirements.

7.2.5. Conclusion

As Figures 13 shows, the capabilities of the two groups are in many ways comparable. However, the IT/data processing companies appear to be better placed to meet the Protocol

requirements in some key respects.

Firstly, IT/data processing companies often deploy their systems on a larger scale, leaving them better prepared to roll out unique identifiers for a high volume product such as tobacco. Secondly, these providers tend to have greater capabilities than the security printing providers regarding the aggregation of product units and the representation of the parent-child relationship in the data being gathered. Thirdly, they tend to be more amenable to their system being operated by other parties, where as the security printing companies prefer to retain direct control, potentially hindering cross border deployment. Finally, the IT/data processing companies tend to make use of widely accepted standards and often design systems to interface with a range of applications, which would facilitate the sharing of track and trace data.

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1. KPMG, Interview programme, January - February 2014

8

Appendix 1
Glossary

AIDC	Auto Identification and Data Capture
COP	Conference of Parties
DC	Distribution Centre
DCTA	Digital Coding & Tracking Association
DNA	Digital Network Analysis
DQSA	US Drug Quality and Security Act of 2013
DRC	Democratic Republic of Congo
EAEPC	European Association of Euro-Pharmaceutical Companies
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPCIS	Electronic Product Code Information Services Standard
ERP	Enterprise Resource Planning
ESM	European Stakeholder Model
EU	European Union
FCC	Federal Communications Commission
FCTC	Framework Convention on Tobacco Control
FDA	US Food and Drug Administration
FMD	European Falsified Medicines Directive
GIRP	European Association of Pharmaceutical Full-line Wholesalers
GTIN	GS1 Global Trade Item Number
GMT	Greenwich Mean Time

IEEE	Institute of Electrical and Electronics Engineers
INB	Intergovernmental Negotiating Body
ISO	International Standards Organisation
iTSCi	ITRI Tin Supply Chain Initiative
ITU	International Telecommunication Union
LAN	Local Area Network
LSPs	Logistics Service Providers
NGO	Non-governmental organization
OECD	Organisation for Economic Co-operation and Development
PGEU	Pharmaceutical Group of the European Union
RFID	Radio-frequency identification
RYO	Roll Your Own
SEC	US Securities and Exchange Commission
SGTIN	Serialised GS1 Global Trade Item Number
SSCC	Serial Shipping Container Code
UID	Unique Identifier
UTC	Coordinated Universal Time
WCO	World Custom Organization
WHO	World Health Organization
WMS	Warehouse Management Systems

Appendix 2
Bibliography

1. Chaudhry and Zimmerman, The Impact of Plain Packaging on the Illicit Trade in Tobacco Products , June 29, 2012

2. Dell'Oro Group, quoted in The Economist, A brief history of Wi-Fi, accessed December 2013, http://www.economist.com/node/2724397

3. EURO-Lex, Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market Text with EEA relevance, accessed January 2014 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0995:EN:NOT)

4. Euromonitor International, Passport: Illicit trade in tobacco products 2012, December 2013

5. European Commission, EU Falsified Medicines - Directive 2011/62/EU, accessed February 2014 (http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm)

6. European Stakeholder Model, About us - Who we are, accessed February 2014 (http://www.esm-system.eu/about-us/who-we-are.ht)

7. FCTC, History of the WHO Framework Convention on Tobacco Control, 2009, accessed December 2013 (http://whqlibdoc.who.int/publications/2009/9789241563925_eng.pdf?ua=1)

8. FCTC, WHO Framework Convention on Tobacco Control, 2003, accessed December 2013 (http://www.who.int/fctc/text_download/en/index.html)

9. FCTC, Protocol to eliminate illicit trade in tobacco, 2013, accessed December 2013, (http://apps.who.int/iris/itstream/10665/80873/1/9789241505246_eng.pdf?ua=1)

10. FCTC, Conference of Parties – Intergovernmental Negotiating Body (INB) third Session's provisional agenda item 4, FCTC/COP/INB-IT/3/INF.DOC./5 – Expert review on the feasibility of an international track and trace regime for tobacco products, 7 May 2009

11. FCTC, Conference of Parties – Intergovernmental Negotiating Body (INB) fourth session's provisional agenda item 3 FCTC/COP/INBIT/4/INF.DOC./1 – Analysis of the available technology for unique markings in view of the global track-and trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products, 22 Feb 2010

12. FDA , Drug Supply Chain Security Act - Title II of the Drug Quality and Security Act of 2013, accessed February 2014 (http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm)

13. Felix Seidel, Review of Electronic and Semi Electronic Timber Tracking Technologies and Case Studies, accessed January 2014 (http://www.itto.int/files/user/pdf/Meeting%20related%20documents/Timber%20Tracking%20Review.pdf)

14. GS1, Research support for an informal expert group on product traceability, Prepared for the European Commission Directorate General Health and Consumers (DG SANCO), October 2013

15. GS1, White paper: The need for global standards and solutions to combat counterfeiting, 2013

16. IFOSSLR, Interoperability and open standards: The key to true openness and innovation, accessed January 2014 (http://www.ifosslr.org/ifosslr/article/view/53/105)

17. International Standard, ISO 12931:2012 - Performance criteria for authentication solutions used to combat counterfeiting of material goods, First edition, June 2012

18. International Tax and Investment Center, The Illicit Trade in Tobacco Products and How to Tackle It, Second Edition, 2013

19. ITU, Definition of "Open Standards", accessed January 2014, (http://www.itu.int/en/ITU-T/ipr/Pages/open.aspx)

20. ITRI website, accessed January 2014 (www.itri.co.uk)

21. KPMG, Project Star 2012 Results, 16 April 2013

22. KPMG, Illicit tobacco in Australia 2013 half year report, October 2013

23. Office of Law Enforcement , Lacey Act, accessed January 2014 (http://www.fws.gov/le/pdffiles/Lacey.pdf)

24. United Nations, Treaty Collections, Chapter IX Health – Protocol to Eliminate Illicit Trade in Tobacco Products, Status as at 10 February 2012

25. US Securities and Exchange Commission - One Hundred Eleventh Congress of the United States of America, An Act - H.R. 4173, accessed January 2014 (http://www.sec.gov/about/laws/wallstreetreform-cpa.pdf)

26. Visiongain, Anti-counterfeit packaging technologies market forecast 2014-2024 and future prospects for leading companies, January 2014

27. World Health Organization (WHO), Framework Convention on Tobacco Control, 2003, accessed December 2013 (http://whqlibdoc.who.int/publications/2003/9241591013.pdf)

28. World Custom Organization (WCO). Illicit Trade Report, 2012

29. WHO Framework Convention on Tobacco Control, Protocol - Ratification, accessed December 2013 (http://www.who.int/fctc/protocol/ratification/en/)

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