Funded by
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Commission

Provision of an Analysis and Feasibility Assessment regarding EU Systems for Tracking and Tracing of Tobacco Products and for Security Features

Member State Project Overview & Briefing

December 2014

Call for tender No EAHC/2013/Health/11
2013/S 068-112544

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These presentation materials were prepared for the 1st meeting of the Sub-Group on Traceability and Security Features of the expert group on Tobacco Policy, and presented on 10 December 2014.

The materials are based on a substantive (+300 pages) draft report, still subject to finalisation and approval by the EU Commission. The slides were prepared for illustrative purposes, and represents only a partial representation of the meeting discussions and presentations.

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Agenda

1 Background & Context

- Project Status
- Deliverables & Tasks
- Constraints & Challenges
- Baseline for Analyses (Problem Statement)
- Key Stakeholders
- Relevant Benchmarks & Trends

2 Key Concepts & Methodology

- Traceability: Key concepts
- Security Features & Authentication: Key Concepts
- Project Methodology
- Stakeholder Engagements

3 Four Options Defined

- Overview of a Traceability Solution
- Description of the Four Traceability Solution Options
- Description of the Four Security Feature Options

4 Analyses and Outcomes

- Implications and Requirements
- Feasibility Concerns
- Additional Solution Considerations
- Cost Benefit Analyses
- Conclusions and Recommendations

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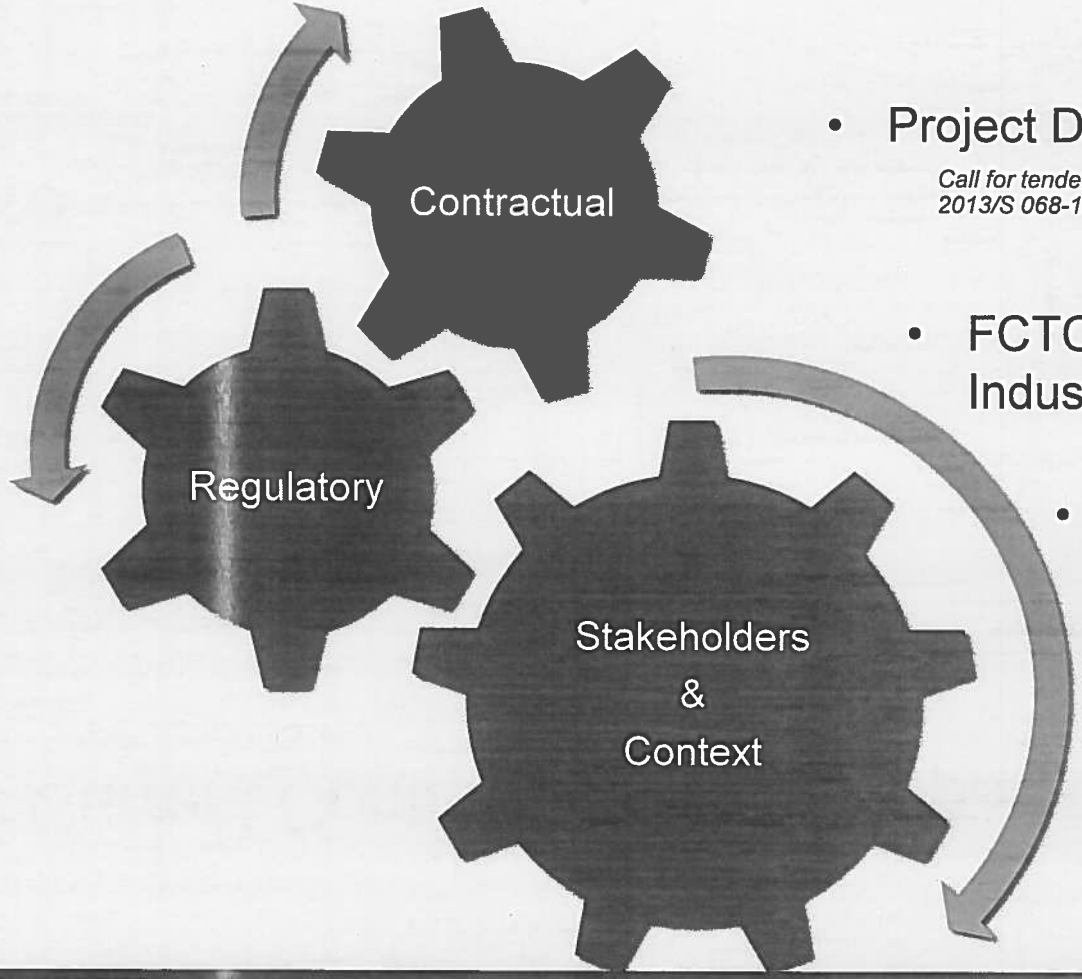
Project Background: Core Components



- Project Deliverables

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  2013/S 068-112544

- FCTC Protocol, TPD, Industry Agreements

- Multiple segments of and unique contexts for each

  - Confidentiality of sensitive information

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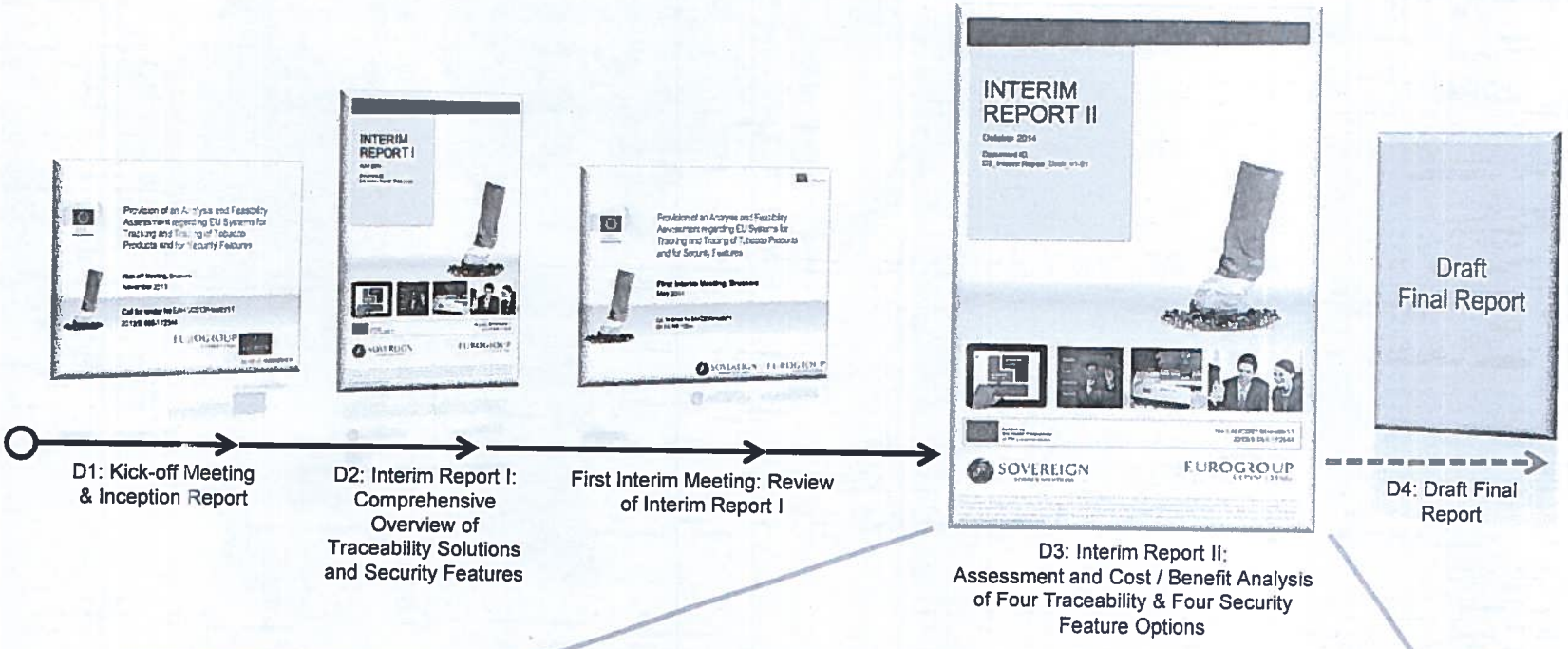
Current Context of Interim Report II



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Contractual Context: Major Deliverables & Related Tasks

1. **Market Overview** of solutions for tracking and tracing of tobacco products:
   a. *Problem Statement*
   b. *Evaluation of current solution landscape*
   c. *Benchmarking of Relevant Solutions in Market*

2. **Market Overview** of available and suitable technologies for secure marking of tobacco products as per TPD requirements
   a. *Consideration of both Visible (Overt), Semi-covert, Covert and Forensic security features*

3. **Four Solution Options** (for both)
   a. Feasibility assessment
   b. Conduct Cost /Benefit Analysis for each
4. **Assess requirements and options for Data Storage Mechanisms (3rd Party)**

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Problem Statement: Critical Success Factors for Traceability Solution

CONTEXT

- TPD
- WHO FCTC Protocol
- Context: Illicit Trade
- Industry Considerations
- Stakeholders: EU Authorities

TRACEABILITY: CRITICAL SUCCESS FACTORS

1	Ensure each pack is marked with a unique identifier (Article 15, § 1);
2	Provide an accurate mechanism for recording the movement (tracking) of tobacco products through the point of manufacture to the last distributor before retail (Article 15, § 5);
3	Support the concept of aggregation (Article 15, § 5);
4	Store data independently (not by the tobacco industry) (Article 15, § 8 and recital 31);
5	Provide that markings are irremovable and indelible (Article 15, § 1);
6	Ensure that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union (Article 15, § 11b);
7	Protect confidentiality and safeguard that decoding and full access to the data storage facilities is limited to authorised authorities and only exceptionally, in duly justified cases, to the tobacco industry, under restrictive conditions (Article 15, § 8);
8	Be compatible with current tobacco production, packaging and the trade environment to minimise the impact on tobacco production, taking into consideration production speeds, equipment, etc. (internal market proportionality obligations);
9	Uphold respect for data protection as specified in the EU legal framework (Directive 95/46/EC) (Article 15, § 10);
10	Be resistant to manipulation (Article 15, § 1);
11	Enable Member States and EU authorities to monitor and survey the market as per respective mandates (general aim of Article 15 and recital 29);
12	Solution components currently being used in a commercial supply chain environment and avoid unnecessary burden for business and/or authorities (Impact assessment considerations).

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Problem Statement: Critical Success Factors for Security Feature

CONTEXT

- TPD
- WHO FCTC Protocol
- Context: Illicit Trade
- Industry Considerations
- Stakeholders: EU Authorities

SECURITY FEATURES: CRITICAL SUCCESS FACTORS

1	Provide a reliable mechanism to authenticate the legitimacy of the product (Article 16, § 1);
2	Have overt elements which provide the modicum of authentication by the consumer without requiring specialised equipment / devices (Article 16, § 1 and impact assessment considerations);
3	Must be tamper proof and irremovable (Article 16, § 1);
4	Ensure that covert elements are accessible by authorised persons and protect commercially sensitive data, if necessary (article 16, § 1 and impact assessment considerations);
5	Provide court-admissible forensic evidence of security feature authentication (Article 16, § 1and recital 29);
6	Be compatible with current tobacco production, packaging trade environment and existing tax regimes and avoid unnecessary burden for business and/or authorities (internal market proportionality obligations).

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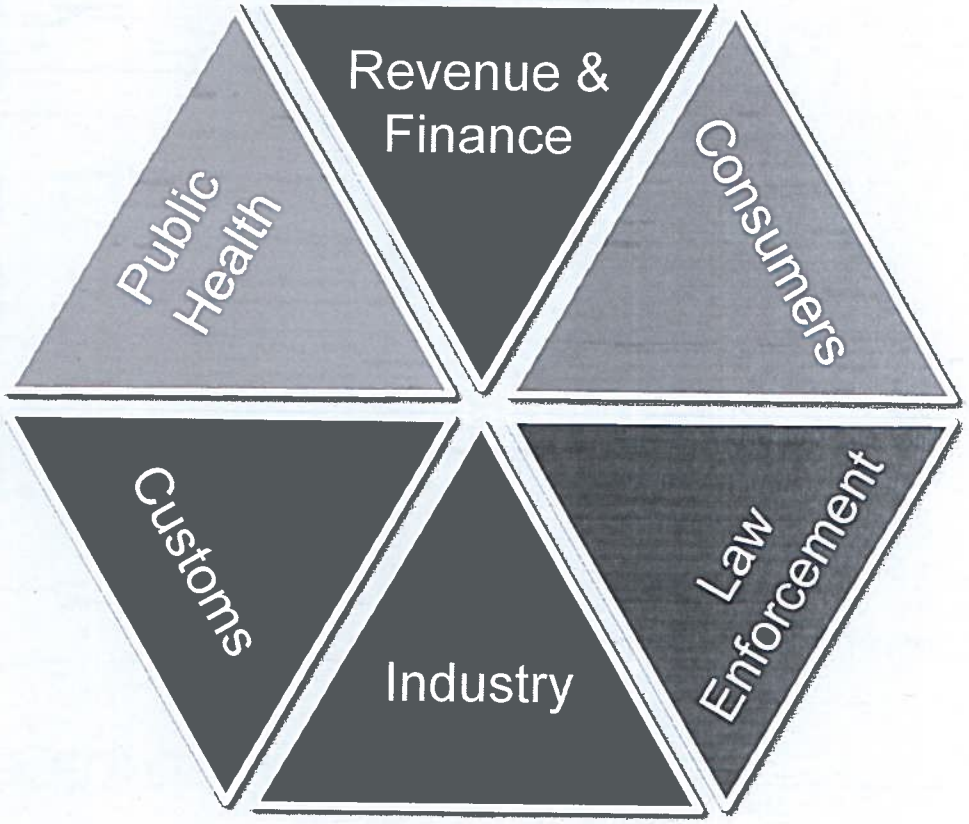
Problem Statement: Multiple & Diverse Stakeholders



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Summary of Stakeholder Requirements

Functional Requirements \ Stakeholders	Law Enforcement	Customs Admin.	Excise Admin.	OLAF	Europol	Interpol	UNODC	WCO	WHO FCTC Secretariat	DG SANCO	DG TAXUD	Consumers
Security feature available to authenticate tobacco products as legitimate	X	X	X	X	X	X		X		X	X	X
Provide support for FCTC Parties to analyse and combat illicit tobacco trade									X			
Traceability and alerting of products which do not comply with national or EU legislation		X		X			X			X	X	
Facilitate investigations in the case of tax fraud	X	X	X	X	X	X					X	

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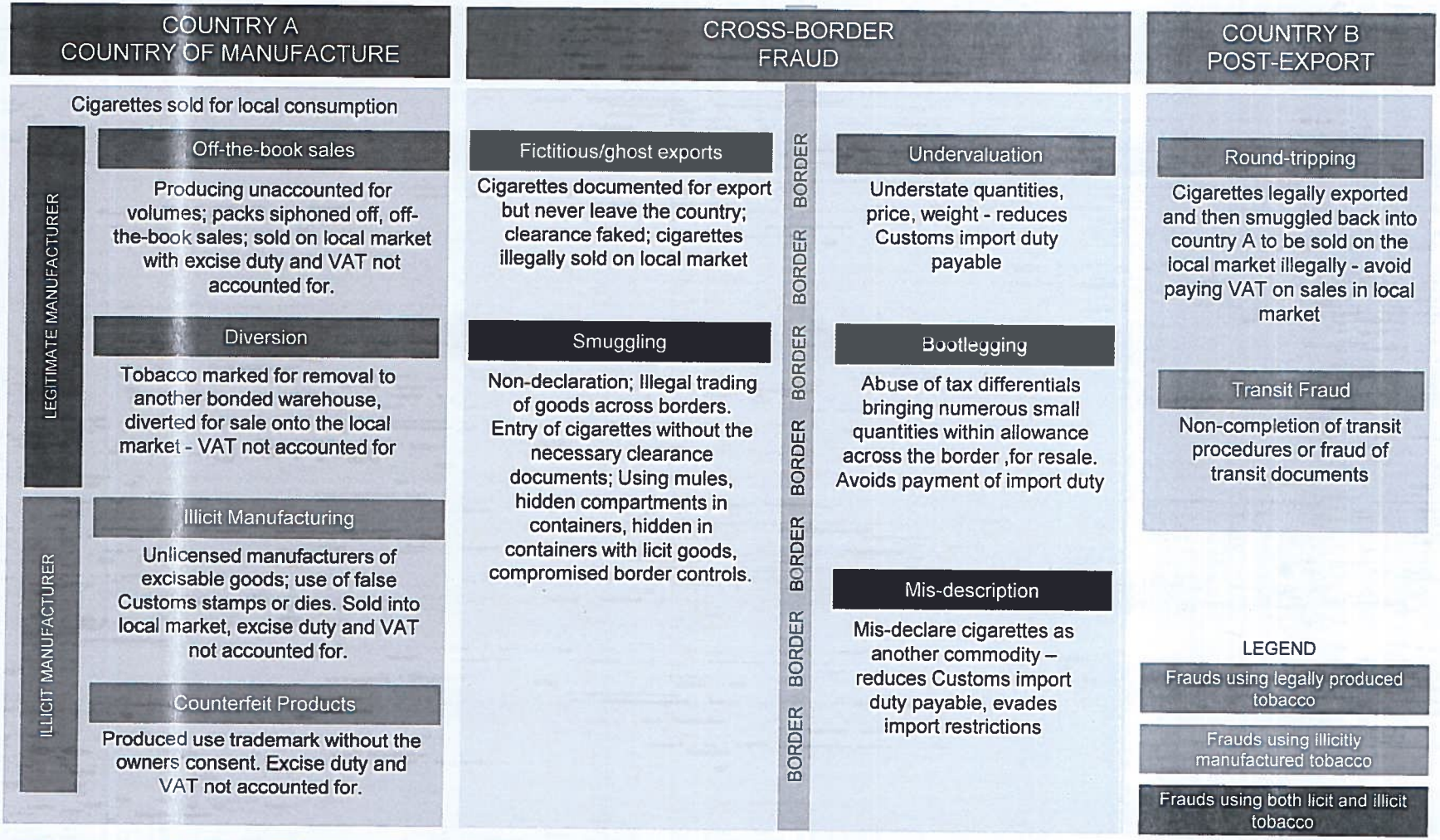
Context: Illicit Trade



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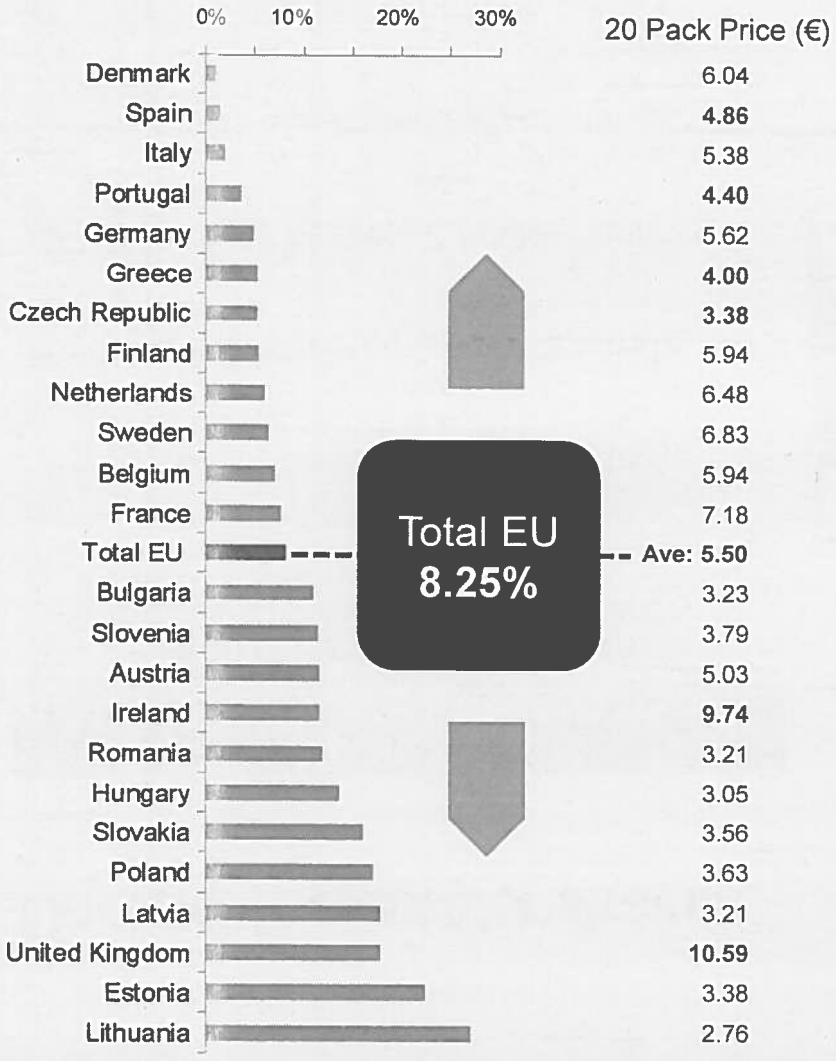
Context: Illicit Tobacco Trade in the EU



- In 2012, for the EU as a whole, illicit trade in cigarettes **represented 8.25%** of total trade.
- Significant variation across EU Member States ranging from 1% through to 27% of the national market
- Counter-intuitively, large proportion of those Member States with cigarette prices higher than the EU average, have lower than EU average illicit trade (as % of national market)

Source: EuroMonitor, 2012

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Context: Project Constraints

CHALLENGES

- ☐ # of Market Participants (274 Identified and 267 directly contacted) Diversity of Stakeholders (solution)
- ☐ Diversity of Industry and Supply Chain Operators (variety of products, large and small)
- ☐ Time & Budget (both are fixed and ambitious)
- ☐ Complexity of subject matter (highly technical)
- ☐ Reliability and impartiality of market data
- ☐ This is a new and emerging market space

APPROACH

- ✓ Multi-disciplined Team
- ✓ Extensive Desk Research
- ✓ Targeted Surveys (electronic #?)
- ✓ Teleconferences with service providers and industry stakeholders
- ✓ Site Visits to functioning track and trace solutions (3 in EU one in South America)
- ✓ Meetings with Client team (CHAFEA, DG SANCO, OLAF, DG TAXUD etc.)
- ✓ Leveraging proven methodologies for analyses and evaluation (MQ)

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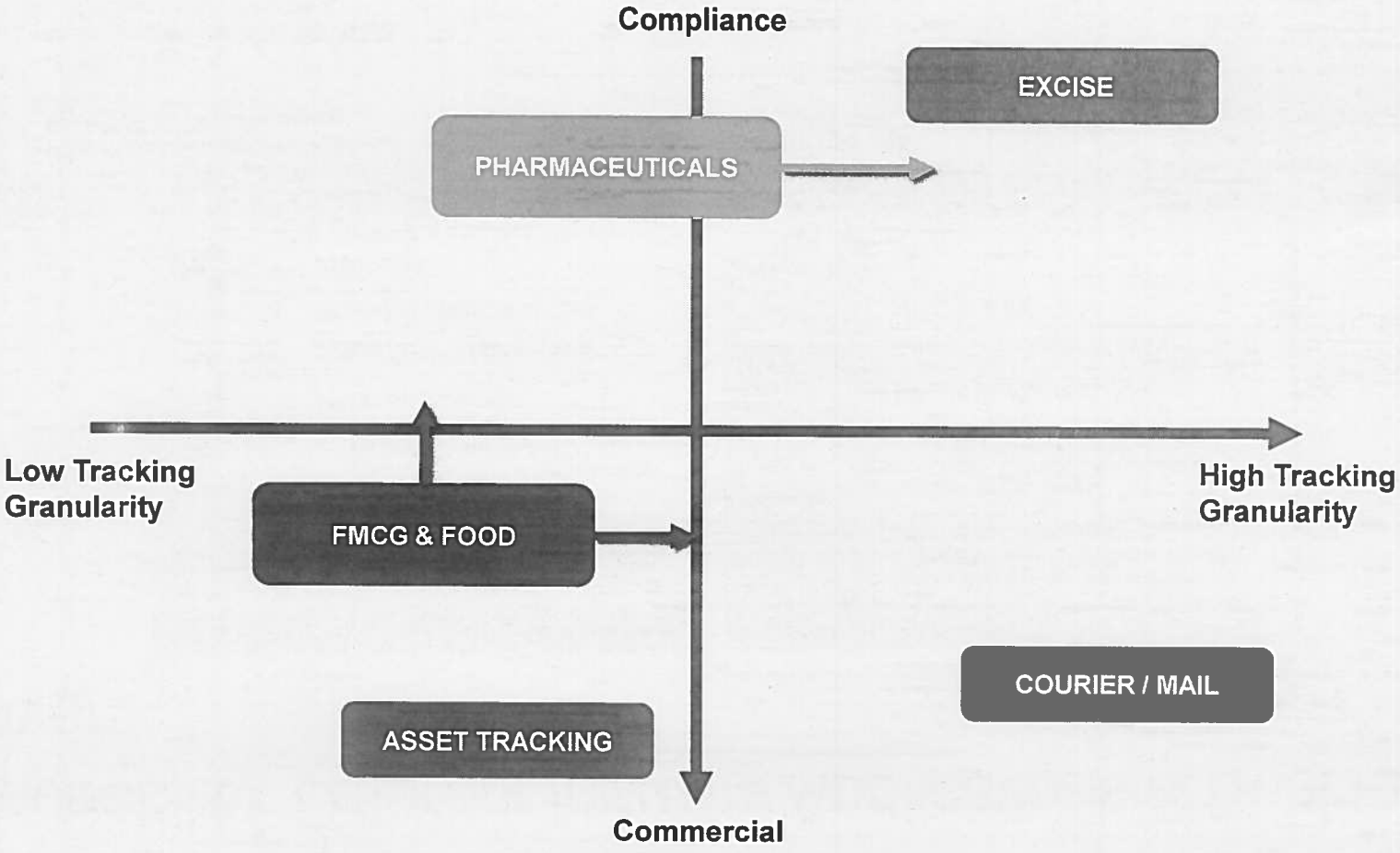
Traceability: Different Industry Applications and Different Business Drivers



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Traceability: Different Industry Applications & Business Drivers

ASSET TRACKING	
APPLICATION	High value but low volume of items Examples: Reefer containers (cold chain), military, fleet management
TECH	• GPS devices • Real-time GSM communication • Business Intelligence
BUSINESS DRIVERS	Efficiency & Security
REGULATION	Supply Chain Security (SCS)
TREND	Escalating Operational Costs
VALUE OF ITEMS	$$$$$$$$$

TOBACCO / EXCISE	
APPLICATION	High volume of low value items Examples: Cigarette packs, Alcohol beverages, Soft drinks
TECH	• Secure markings • Mobile Enforcement devices • Digital Security technologies
BUSINESS DRIVERS	Tax and Government Policies
REGULATION	Supply Chain Security (SCS)
TREND	FCTC (Tobacco)
VALUE OF ITEMS	$$

PHARMACEUTICALS	
APPLICATION	High value pharmaceutical products Examples: Individual company solutions
TECH	• Secure Marking • Covert authentication techniques • Spectroscopy Techniques
BUSINESS DRIVERS	Brand Integrity and Public Health
REGULATION	ePedigree, Falsified Medicines
TREND	Increasing threat of counterfeits
VALUE OF ITEMS	$$$$$

COURIER / MAIL	
APPLICATION	Hetrogenous items mixed value Examples: Fedex, UPS, DHL, Postal service
TECH	• Direct Marking • High speed scan & sort • Integration & Customer Apps (consumer & commercial)
BUSINESS DRIVERS	Customer Service
REGULATION	B2B agreements, Int'l standards
TREND	High eCommerce volumes growth
VALUE OF ITEMS	$ - $$$$$

FMCG & FOOD	
APPLICATION	Still on-going / point to point Examples: Cold Chain, Meat and Fish
TECH	• Direct Marking • RFID • Tamper Band Seals • Freshness Indicators
BUSINESS DRIVERS	Supply Chain Efficiency
REGULATION	Industry driven initiatives
TREND	Counterfeiting and Theft
VALUE OF ITEMS	$

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Example: Seafood Traceability

Overview

- Philosophy: Create the world's most trusted seafood traceability system that empowers consumers and rewards producers.
- Designed and tested in partnership with a network of fish harvesters, fishing organizations and seafood businesses on Canada's Pacific and Atlantic coasts.
- Securing the supply chain by: Coding (marking)at source, uploading tracking and tracing information and enabling user authentication via mobile device

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Context: Emerging Best Practice

	Dimension	Description
	Entity Centric	▪ Focuses on the parties behind the transaction ▪ Incorporates company/industry best practice ▪ Entity-based assurance measures, policies and standards ▪ Holistic view of entities (e.g., across tax types)
	Collaborative	▪ Considers existing relationships, interfaces and interaction points. ▪ Highly communicative, interlinked with a high degree of information sharing ▪ B-2-B, G-2-G, G-2-B
	Data Rich	▪ Utilizing all of the relevant data that exists ▪ Linking data in meaningful ways ▪ Movement data, meta data
	Standards Based	▪ Using a standards approach to security measures (ISO like) ▪ Incorporating industry standards (GS1, EPCIS etc.)
	Whole of Government	▪ Incorporates and integrates with Other Government Agencies (OGA) in terms of regulatory authority, systems and processes (e.g., joint inspections) ▪ Data entered once is shared by everyone
	Security Infrastructure (People, Process Technology)	▪ Provides the infrastructure to embed "trust" ▪ Digital, physical, business processes, personnel
	Multiple Stakeholder Needs	▪ Addresses the needs of multiple stakeholders simultaneously and attempts to link benefits (e.g., food safety authority to consumer)

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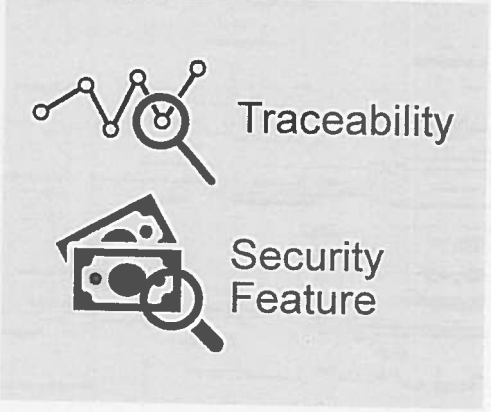
Feasibility Study Key Findings (Preliminary)

1. **Implementation of traceability is feasible**
   - Technology exists
   - Diverse market of suppliers
   - Emerging technologies & solutions are proliferating
   - Traceability is a growing trend globally
   - The needs of multiple stakeholders can be met



2. **There is no one size fits all solution (or provider)**
   - There are a multitude of ways this can be done (with differing results, impact and consequence)

3. **Some key decisions need to be further explored and considered and this report provides a key input into that process.**

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Executive Summary and Member State Briefing (Part 2)

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Traceability: Key Principles

9 Status of goods that are made available for retail (end-point of tracking events).

8 Receipt of the Goods by another party (the purchaser);

7 Repackage events to prepare a consignment for shipping and despatch by the seller;

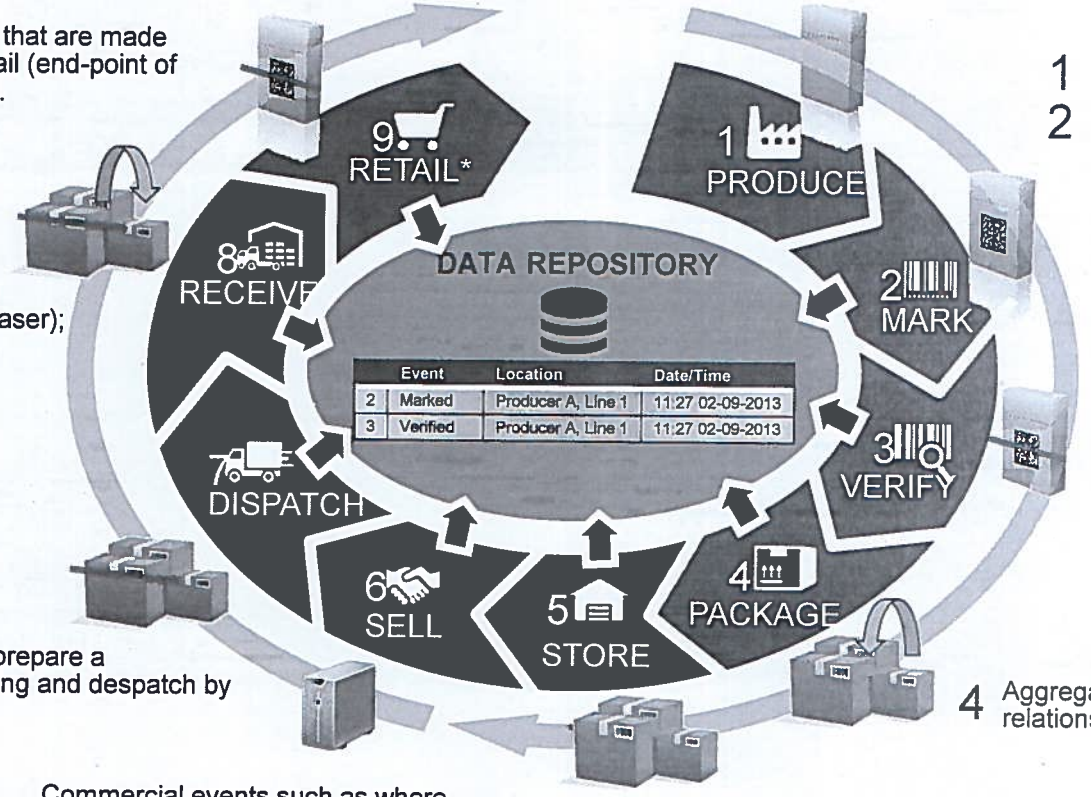
6 Commercial events such as where legal transfer of ownership / status occurs;

5 Warehousing of items as goods are checked-in and checked-out of storage facilities;

4 Aggregation events creating a one to many relationship;

3 Mark Verification on production line for quality control

1 Traceability marking at point of
2 production which includes time, date an location



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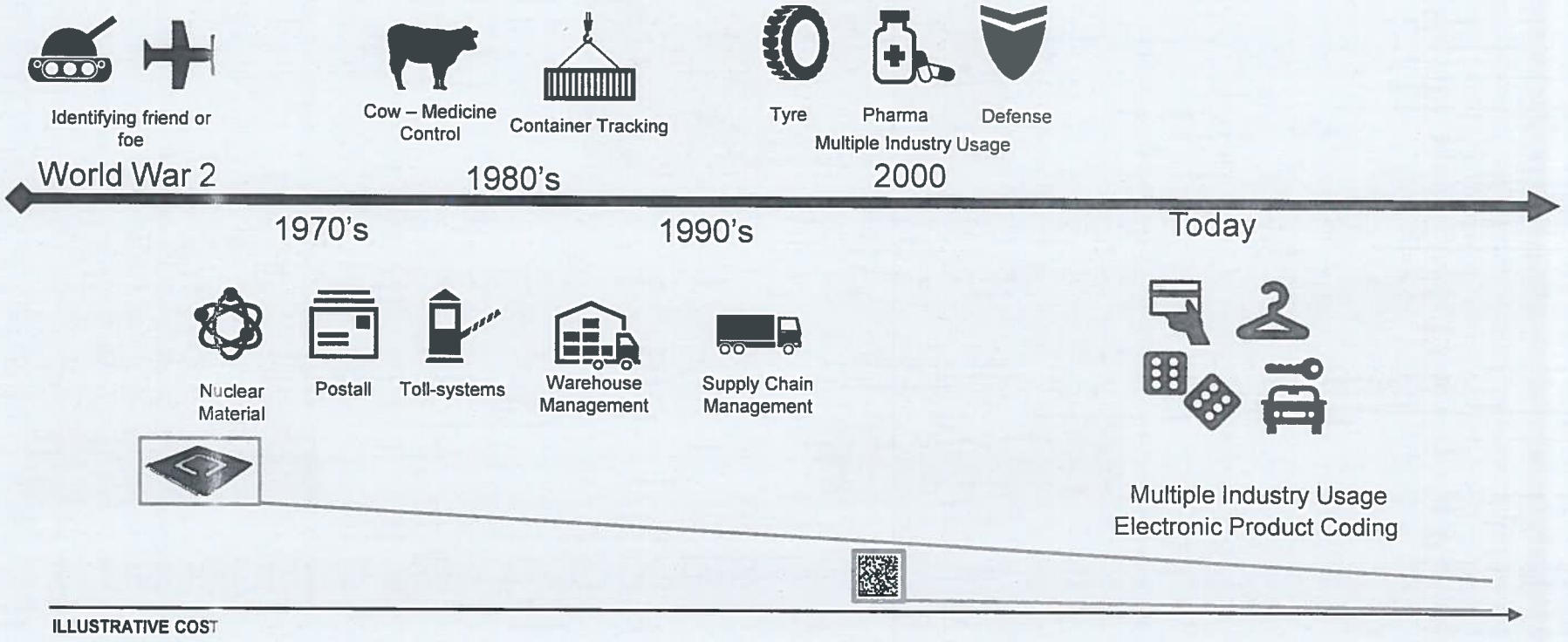
Paving the way for Traceability

RFID: Radio-frequency identification is the wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. A signal is sent to a transponder, which wakes up and either reflects back a signal (passive system) or broadcasts a signal (active system).



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Traceability: Key Concepts

Unique Identifier

An identification code that is attached to an item or product which is **exclusive to that particular product**. For many products this can be a serial number, numeric or alphanumeric code or similar identification.

Serialisation

Serialisation ensures each item is **marked with a unique identifier** so that it can be monitored from the point of production up to the final sale, including each step of the process, creating a time and location history for every step.

Track & Trace

Enable a product's status to be captured through the supply chain, and to retrospectively identify and verify its history, path and location. Solutions typically include elements for:

- Associating products or materials with unique identifiers (UIDs);
- Capturing events at various points in the supply chain; and
- Performing analytics and reporting on the information.
- Some solutions include messaging to share information with regulatory agencies or trading partners, and some also support capabilities for product authentication.

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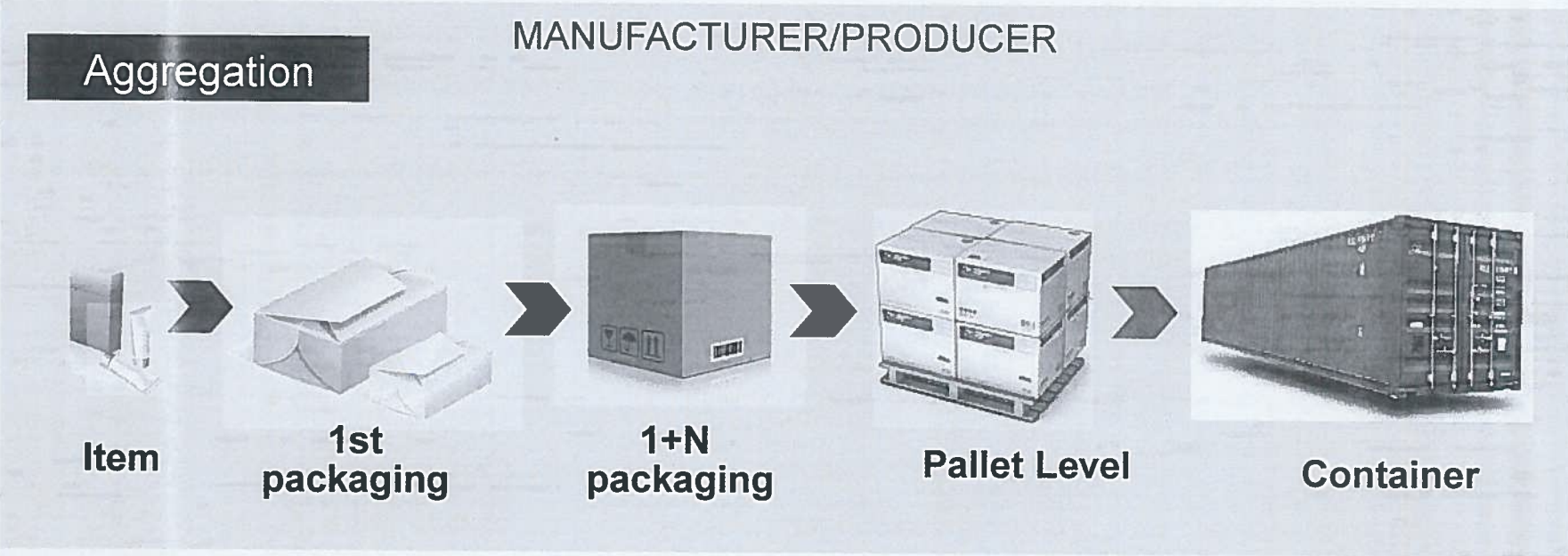
Traceability: Key Concepts



- Create many-to-one (parent-child) relationship
- Facilitate the tracking and tracing of goods over the supply chain (collaboration)
- Compliance with standards and norms across industries

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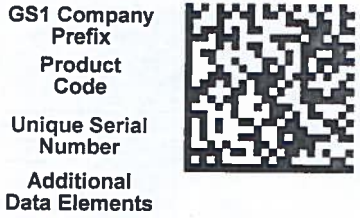
Types of Information Encoding on Products:

EAN-13 Barcode used for Retail

ECC 200 Data Matrix used for Traceability



Retail barcodes and identifiers

- Unique to a product level (not pack level)
- Intended for stock control and Point of Sale
- Easily readable by retail scanner

Traceability Encoding

- Unique to individual pack level
- Contains all std barcode data, plus allows for additional data elements such as:
  - Manufacture location (TPD requirement)
    - Company, Site number, Address, Country
  - Date and time of manufacture
  - Expiration date
- Requires modern device for scanning

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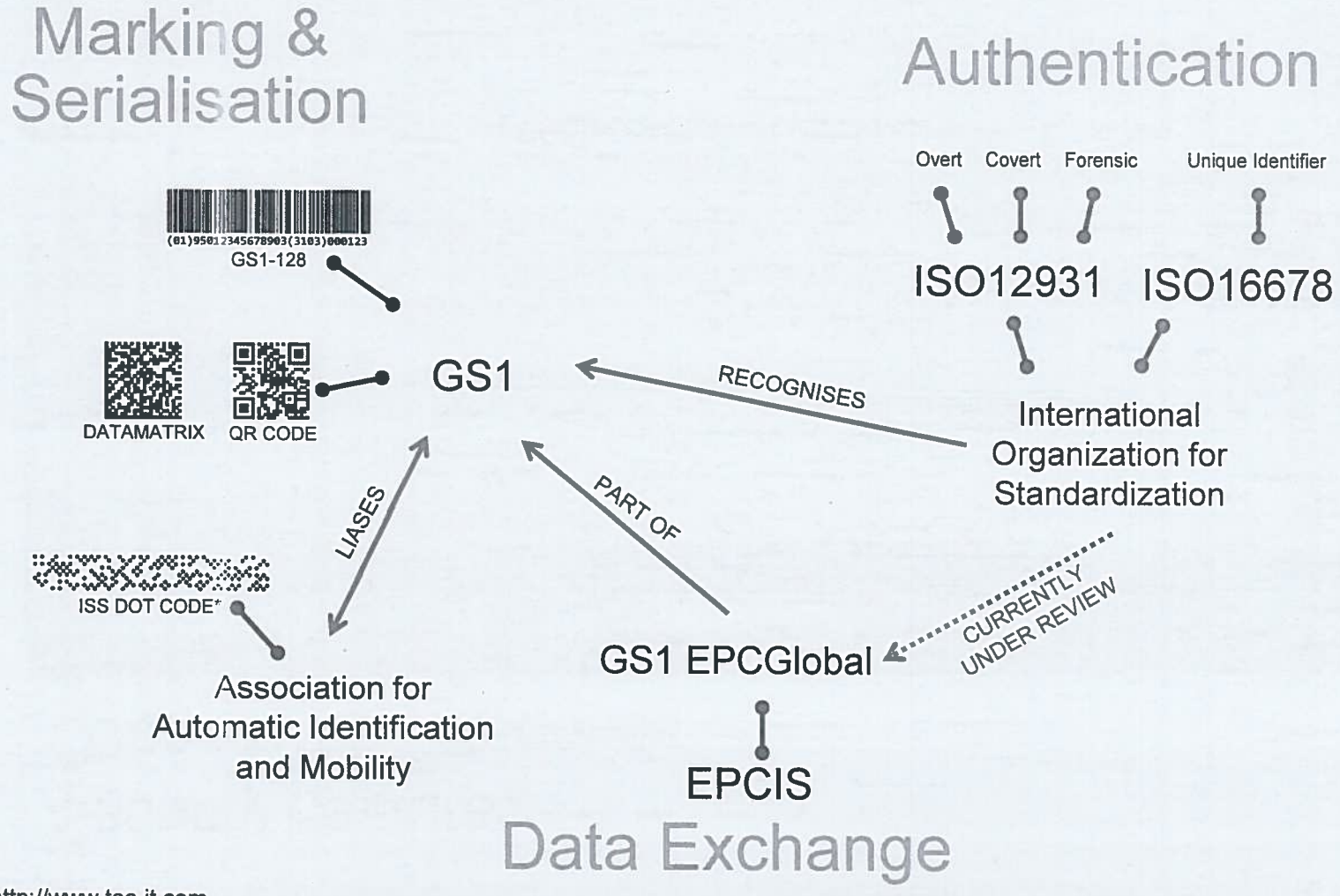
Some Relevant Standards and Bodies



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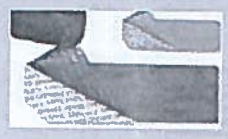
Security Features: Overview of Categories

Category	Description	Examples
Overt	Security features that can be verified by naked eye, such as colour changing inks, holograms, latent images, watermarks and security threads. Almost always a visible security feature.	
Semi-Covert	Security features requiring a simple tool that does not require limited training such as UV Fluorescent inks and specialised print techniques (e.g. latent image, and a simple device (e.g. UV torch).	
Covert	Security features that can be authenticated by only using a dedicated and specialised electronic readers for authentication, such as proprietary taggants or special invisible inks.	
Forensic	Security features including forensic markers identified through laboratory analysis providing irrefutable evidence that could be submitted as evidence in a court of law.	
Physical Security / Tamper Evident	Security features, including techniques to provide tamper evidence and elements to prevent transfer and reuse.	
Emerging	Security features using material fingerprinting and entropy-based / chaometric authentication techniques. These can include visible elements which provide covert and semi-covert elements which require specialised techniques to authenticate.	

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Methodology: Market Overview

OBJECTIVES

1. Ability to determine "real" vs. "marketing" among hundreds of companies
2. Logical method of defining the market based on industry best practice
3. Provide confidentiality to survey participants and still be able to communicate relevant findings
4. Develop a configurable, thorough and granular model for analyses
5. Do so with limited resources for travel, site visits and face-to-face meetings

Comprehensive Overview: Track & Trace Solutions

Comprehensive Overview: Security Features

1. **Market Overview of solutions for tracking and tracing of tobacco products:**
   a. *Problem Statement*
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1st Phase: Research Methodology

Market Research

- Industry publications, trade/industry associations used to identify potential participants
- Extensive web-based searches and direct contact (telephone and email) to invite participation in the survey

Surveys (4)

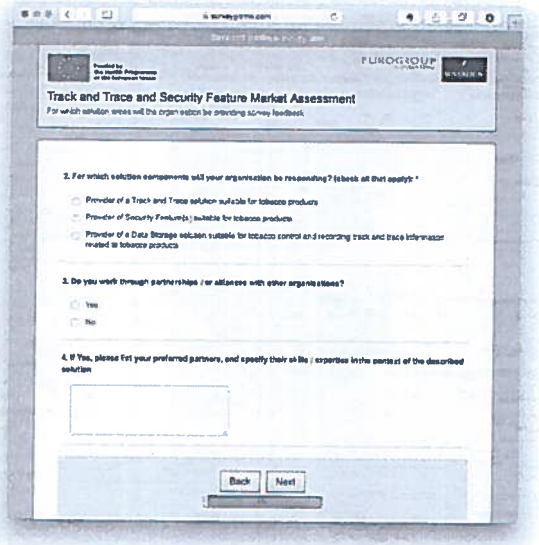
- 4 detailed surveys developed allowing structured responses as well as free form (apples to apples)
- Included key inputs from relevant technical standards

Validation

- Follow-up emails, and one-on-one conference calls were set up with with participants throughout the survey period to encourage responses and clarify data points.
- No one was turned down from being able to provide input

Analyses

- Consolidating the data (responses) in order to analyse the information collected.
- Scoring and criteria weighting was conducted via multi-disciplined Team (technical, functional domain) workshops where key issues and criteria were vetted in detail and consensus was reached



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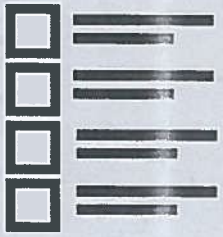
Research Methodology Criteria



Survey Process:

- On-line survey tool
- Companies were given between 4-6 weeks to complete the assessment, with numerous reminders sent to ensure they completed the assessment
- Survey deadlines extended multiple times

Participants:

- Of the 274 identified participants, contact information was obtained for 267
- The respondents included a mix of both established and emerging companies, ranging from 2 years in operation to 200 years.

Response Rate:

- The survey response rate showed a high falloff
- From the group of 267 participants that were successfully contacted, the online survey was viewed 165 times
- In total, 43 fully completed survey responses were received

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Project Timeline: Stakeholder Engagement

Mar – April 2014: Solution Provider Survey
- 274 Organisations
- SurveyGizmo

August 2014 – Site visit to Manufacturers of Other Tobacco Products
- Pöschl Tabak
- E-mail communications

August 2014 – Current Considerations for non-cigarette tobacco products
- House of Oliver Twist, ECMA
- Tele-Conference and E-mail communications

August 2014
Second Survey to gather feedback on security feature packages
- 14 Security Feature Providers
- Tele-Conference and E-mail communications

Jul – Sep 2014 – Survey to Tobacco Manufacturers operating production facilities in Europe
- House of Oliver Twist, ECMA
- Tele-Conference and E-mail communications

Sep – Oct 2014
Follow up With Security Feature Solution Providers
- Alpvision: & Arjowiggins
- Tele-Conference

Sep – Oct 2014 – DCTA Members – Experience with Track and Trace
- DCTA, with feedback received directly from BAT and JTI
- Tele-Conference and E-mail communications

TRACEABILITY AND SECURITY FEATURE SOLUTION PROVIDERS

TOBACCO MANUFACTURERS

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Stakeholder Engagements

August 2014: Workshop with ETV Association in Mönchengladbach
- European Tobacco Wholesalers Association (ETV), including Bundesverband Deutscher Tabakwaren-Großhändler und Automatenaufsteller (BDTA)
- Telephone, Email and on-site Workshop

August 2014 – Site Visit in Portugal
- [redacted]
- On-site Visit

August 2014: Second Survey to gather feedback on security feature packages
- 14 Security Feature Providers
- Tele-Conference and E-mail communications

Mar 2014 – WCO FCTC Secretariat
- [redacted]
- Tele-Conference and E-mail communications

Mar - Sep 2014 –Understand GS1 organisation structure, potential impact on manufacturers and distribution chain economic operators
- GS1 Global
- Tele-Conference and E-mail communications

Oct 2014 - Data Storage Domain Providers
Obtain indicative cost information for operating and hosting a GS1 certified information service (for estimating the costs associated with the Data Storage Providers
- Microsoft Portugal, SAP
- Email and Telephone

Oct 2014 – Distribution Chain Operators Experience during DCTA conducted pilots
- Cobeltab, Tobaccoland, Jan de Rijk Logistics (companies suggested by DCTA)
- E-mail communications

DISTRIBUTION CHAIN ECONOMIC OPERATORS | **DATA STORAGE DOMAIN PROVIDERS** | **OTHER ORGANISATIONS**

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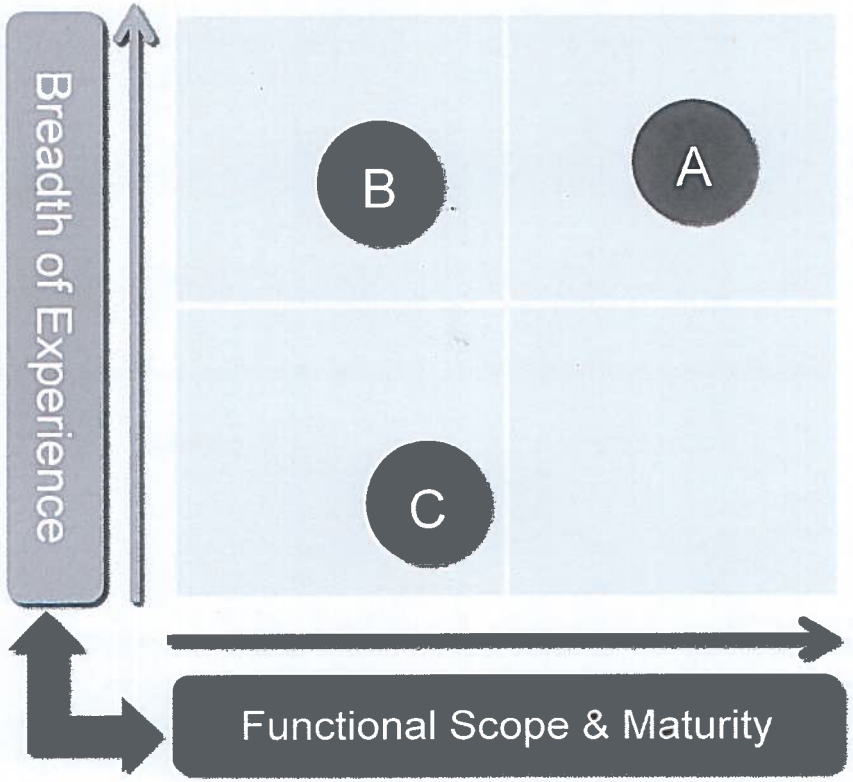
Feasibility Study Methodology:
The Assessment Matrix - Dimensions and Evaluation Criteria



Project uses an Assessment Matrix framework to assess players within this market. It provides an assessment on two dimensions:

Functional Scope & Maturity – assessment of the proposed offering vis-à-vis problem statement

Breadth of Experience – summarises factors on relevant implementations and experience as a proxy for the ability to deliver on the EU's future traceability requirements

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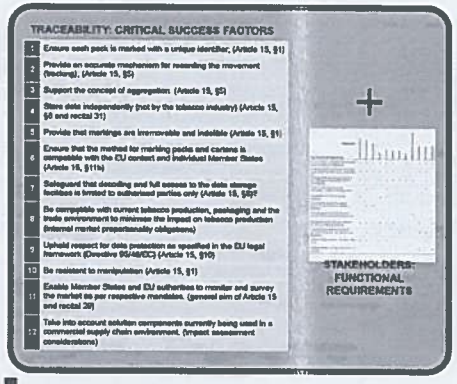
Translating the Problem Statement into the Assessment Criteria

CRITICAL SUCCESS FACTORS
Problem Statement

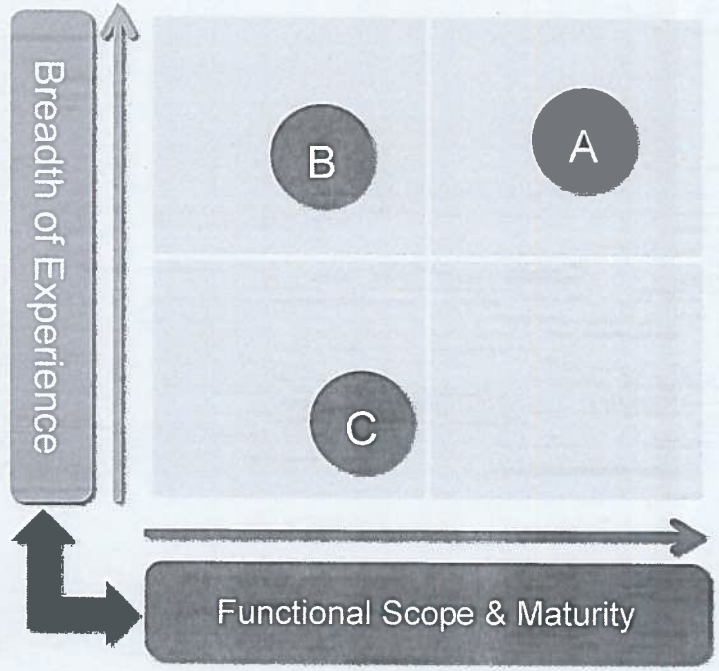
NATURE OF TOBACCO INDUSTRY

CONSIDERATION OF STANDARDS



TRADE FLOWS MFG EQUIPMEN T

GS1 EPCIS ISO



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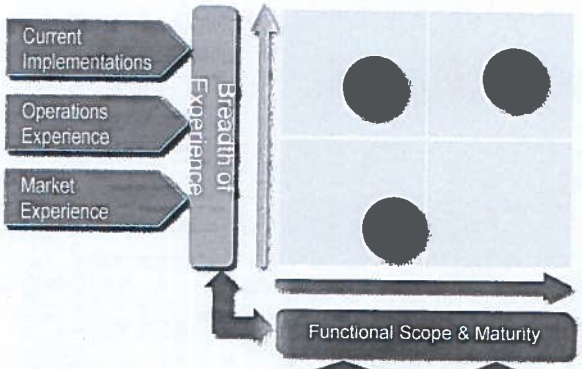
Assessment Criteria comprise multiple Sub-Criteria, each evaluated using Survey Questions and Responses

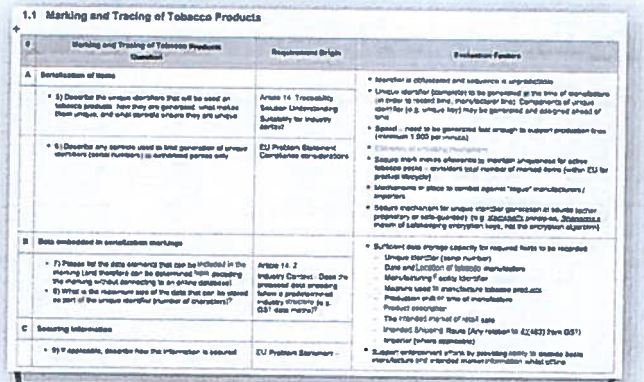


1 Each Dimension Criteria is made up of multiple Sub Criteria

Proposed Offering

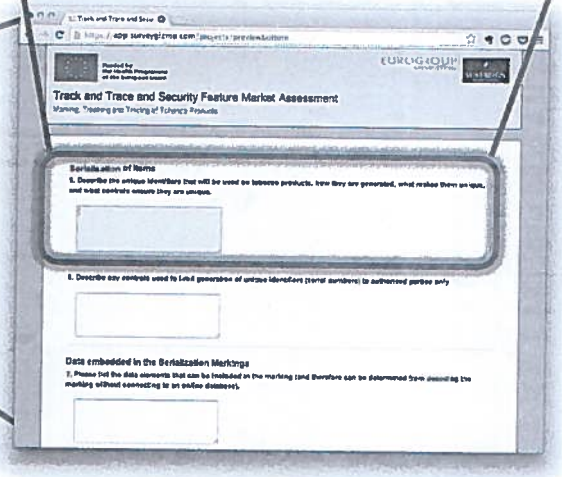
- A1: Serialisation, Data & Security
- A2: Pack Encoding & Marking
- A3: Carton Encoding & Marking
- A4: Tertiary Packaging Marking
- A5: Aggregation Method
- A6: Tobacco Industry Considerations
- A7: Distribution chain information Integration
- A8: Query and Tracing Tools
- A9: Oversight For Government & QA

2 Each Sub Criterion is rated using info from one or many survey questions



3 Survey responses are evaluated using Evaluation Factors

SURVEY EVALUTION FACTORS



SURVEY QUESTIONS

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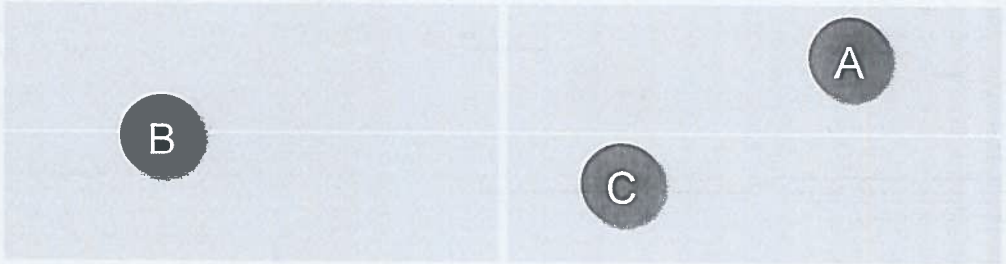
Traceability Solution Providers: Criteria and Sub-Criteria

Current Implementations
- **A1:** Proven Solution Components
- **A2:** Existing Fit for Tobacco Domain
- **A3:** Implementation Experience (General)
- **A4:** Number of Sites
- **A5:** Number of Marked Items
- **A6:** Holds Certifications and Standards

Operations Experience
- B1: Experience operating solution
- B2: Experience Providing Manufacturing Support / Maintenance
- B3: Experience as Equip. Provider
- B4: Experience as Software Provider
- B5: Experience in Tobacco Domain

Market Experience
- **C1:** Breadth of Experience
- **C2:** Years Company in Operation

Dimension: Breadth of Experience



Dimension: Functional Scope & Maturity

Proposed Offering
- A1: Serialisation
- A2: Pack Encoding & Marking
- A3: Carton Encoding & Marking
- A4: Tertiary Packaging Marking
- A5: Aggregation Method
- A6: Tobacco Industry Considerations
- A7: Distribution chain information Integration
- A8: Query and Tracing Tools
- A9: Oversight For Government & QA

Understanding
- **B1:** Use of Standards and Interoperability
- **B2:** Integration with EU Solutions
- **B3:** Synergies with Security Feature
- **B4:** Business Intelligence and RM Tools

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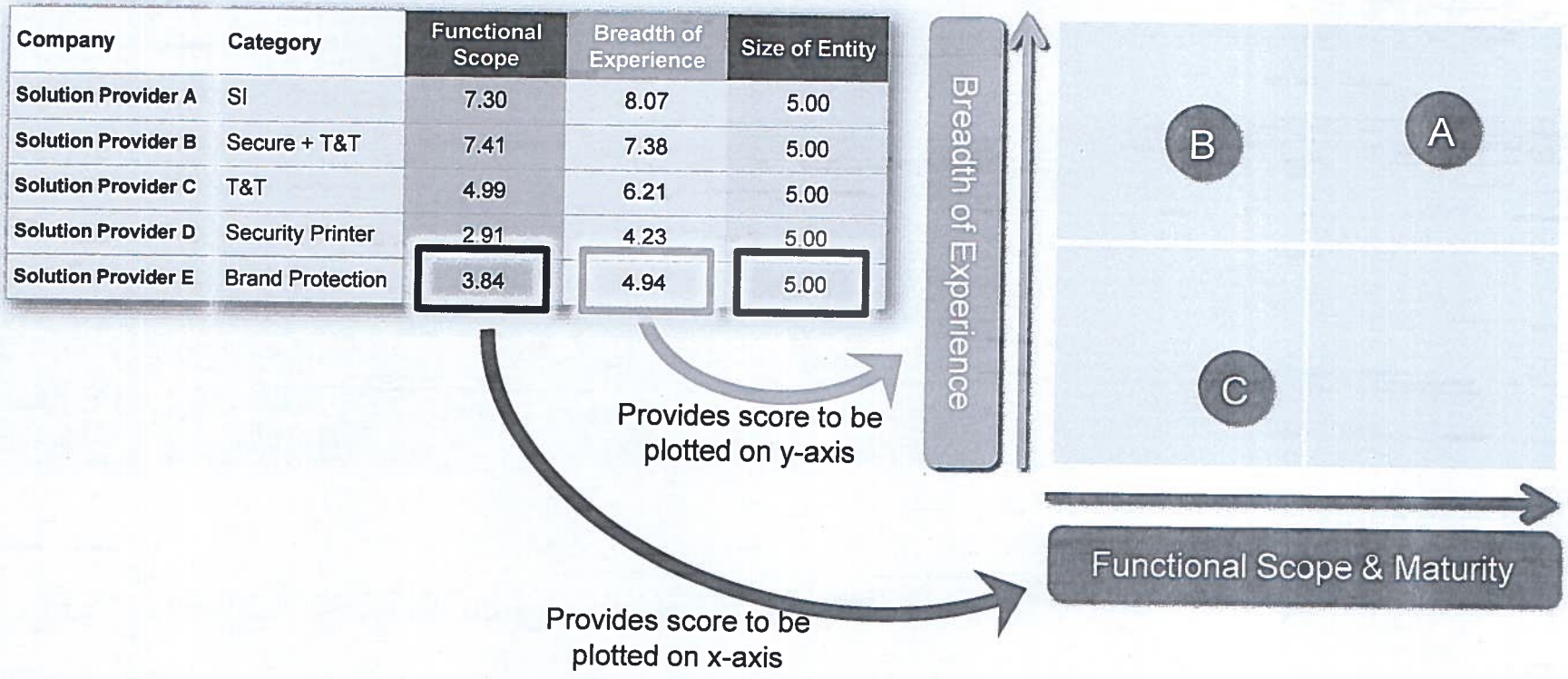
Solution is then plotted using the Dimension Scores for Completeness of Vision and Ability to Execute

Company	Category	Functional Scope	Breadth of Experience	Size of Entity
Solution Provider A	SI	7.30	8.07	5.00
Solution Provider B	Secure + T&T	7.41	7.38	5.00
Solution Provider C	T&T	4.99	6.21	5.00
Solution Provider D	Security Printer	2.91	4.23	5.00
Solution Provider E	Brand Protection	3.84	4.94	5.00



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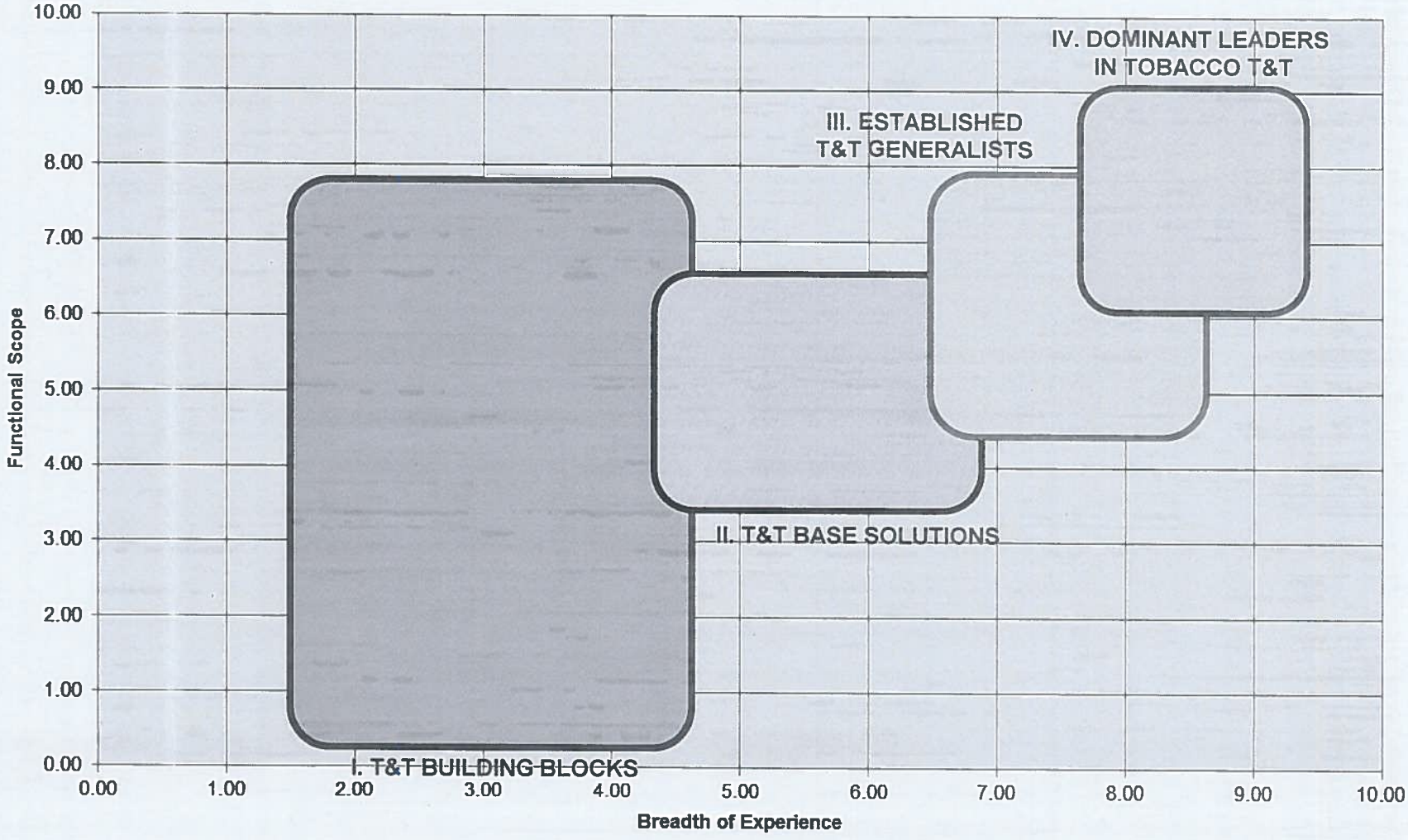
Traceability Solutions: Results



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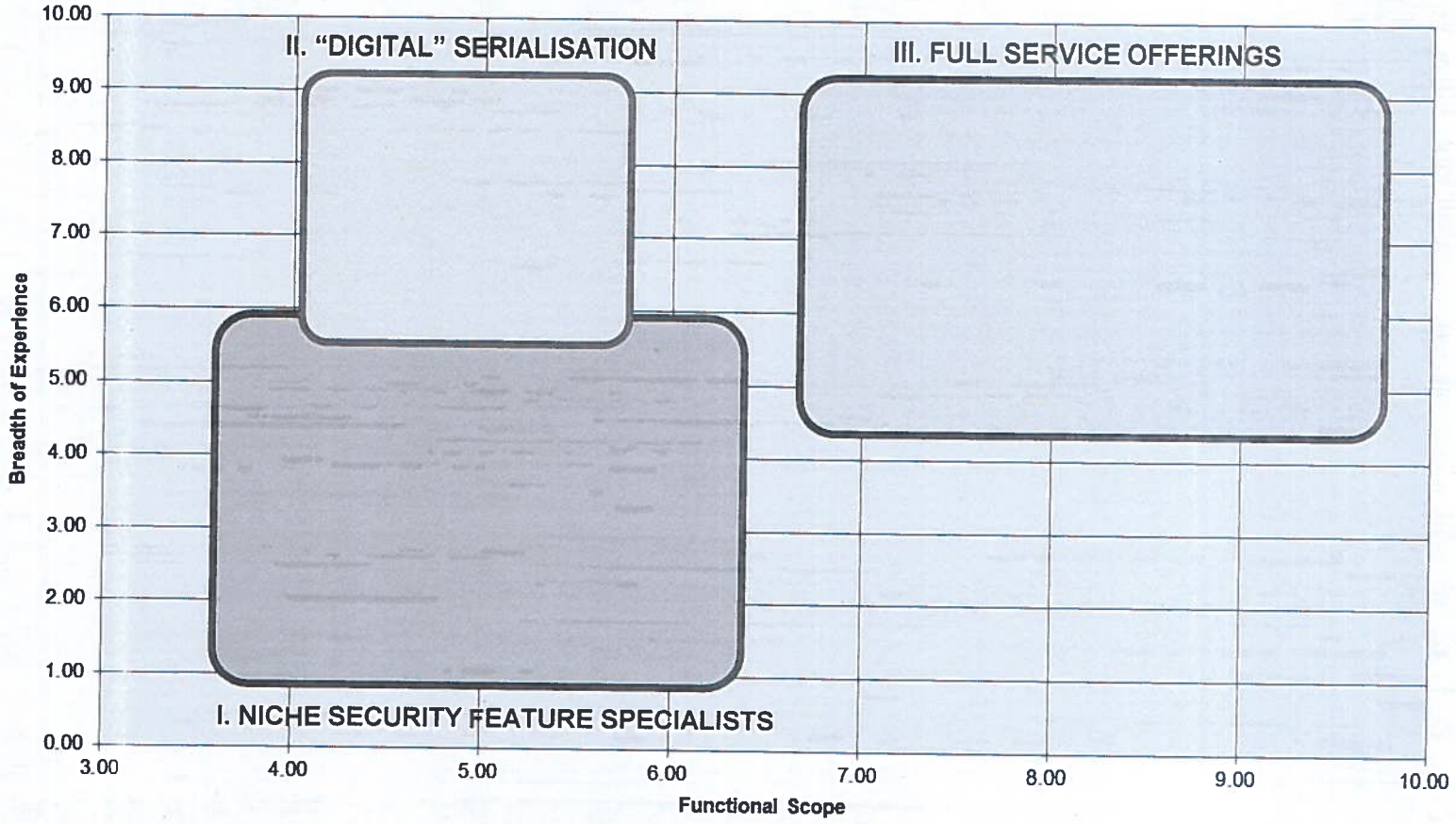
Security Feature Solutions: Results



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Market Assessment Outcomes

1. **Implementation of traceability and secure marking is feasible**
   - There are no technical impediments to the Protocol or TPD
   - Is already being done by multiple players and in several locations within the EU and outside.

2. **Market of technology solution providers exists and is growing**
   - There is a diverse market of suppliers
   - Emerging technologies and solutions are proliferating

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Funded by
the Health Programme
of the European Union

European
Commission

Provision of an Analysis and Feasibility Assessment regarding EU Systems for Tracking and Tracing of Tobacco Products and for Security Features

Executive Summary and Member State Briefing (Part 3)

December 2014

Call for tender No EAHC/2013/Health/11

2013/S 068-112544

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These presentation materials were prepared for the 1st meeting of the Sub-Group on Traceability and Security Features of the expert group on Tobacco Policy, and presented on 10 December 2014.

The materials are based on a substantive (+300 pages) draft report, still subject to finalisation and approval by the EU Commission. The slides were prepared for illustrative purposes, and represents only a partial representation of the meeting discussions and presentations.

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Agenda

1 Background & Context

- Project Status
- Deliverables & Tasks
- Constraints & Challenges
- Key Stakeholders
- Baseline for Analyses (Problem Statement)
- Relevant Benchmarks & Trends

2 Key Concepts & Methodology

- Traceability: Key concepts
- Security Features & Authentication: Key Concep s
- Stakeho der Engagements
- Project Methodology
- Summary of Market Overview

3 Four Options Defined

- Overview of a Traceability Solution
- Description of the Four Traceability Solution Options
- Description of the Four Security Feature Options

4 Analyses and Outcomes

- Implications and Requirements
- Feasibility Concerns
- Additional Solution Considerations
- Cost Benefit Analyses
- Conclusions and Recommendations

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Scope of Assessment – Four Options (x2)

- **Why Four Options?**
  - Contract scope: contractual deliverable
  - Provides range to explore feasibility and cost/benefit of a range of options

- **How were the Four Options determined? Our objectives were as follows:**
  - Distill out the relevant considerations-- requiring further discussion and evaluation
  - Meet the needs of multiple stakeholders (health, law enforcement, large and small manufacturers)
  - Meet the requirements of the problem statement
  - Propose different governance models
  - To be flexible in accommodating all of the above

- **Are there only Four Options?**
  - Growing prevalence of standards and interoperability increases solution flexibility
  - Some elements "modular" and therefore choice in manner implemented
  - Therefore, any number of configurations could be proposed, combining / blending elements from 4 options

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NAVIGATION AID

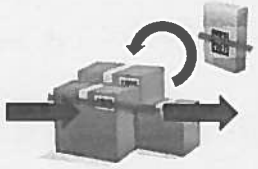
Overview of a Traceability Solution

Tobacco Manufacturing Facilities

- Serialisation of tobacco items marked with a unique identifier
- Production verification
- Security feature
- Aggregation

Distribution Economic Operators

- Distribution events up to the last economic operators before first point of retail



Data Storage Providers

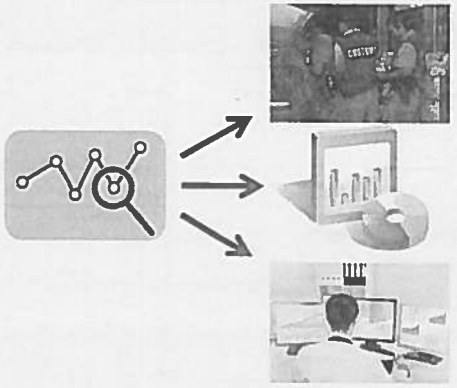
- Independent storage of traceability data

Member State Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with Member State systems

European Union Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with EU systems



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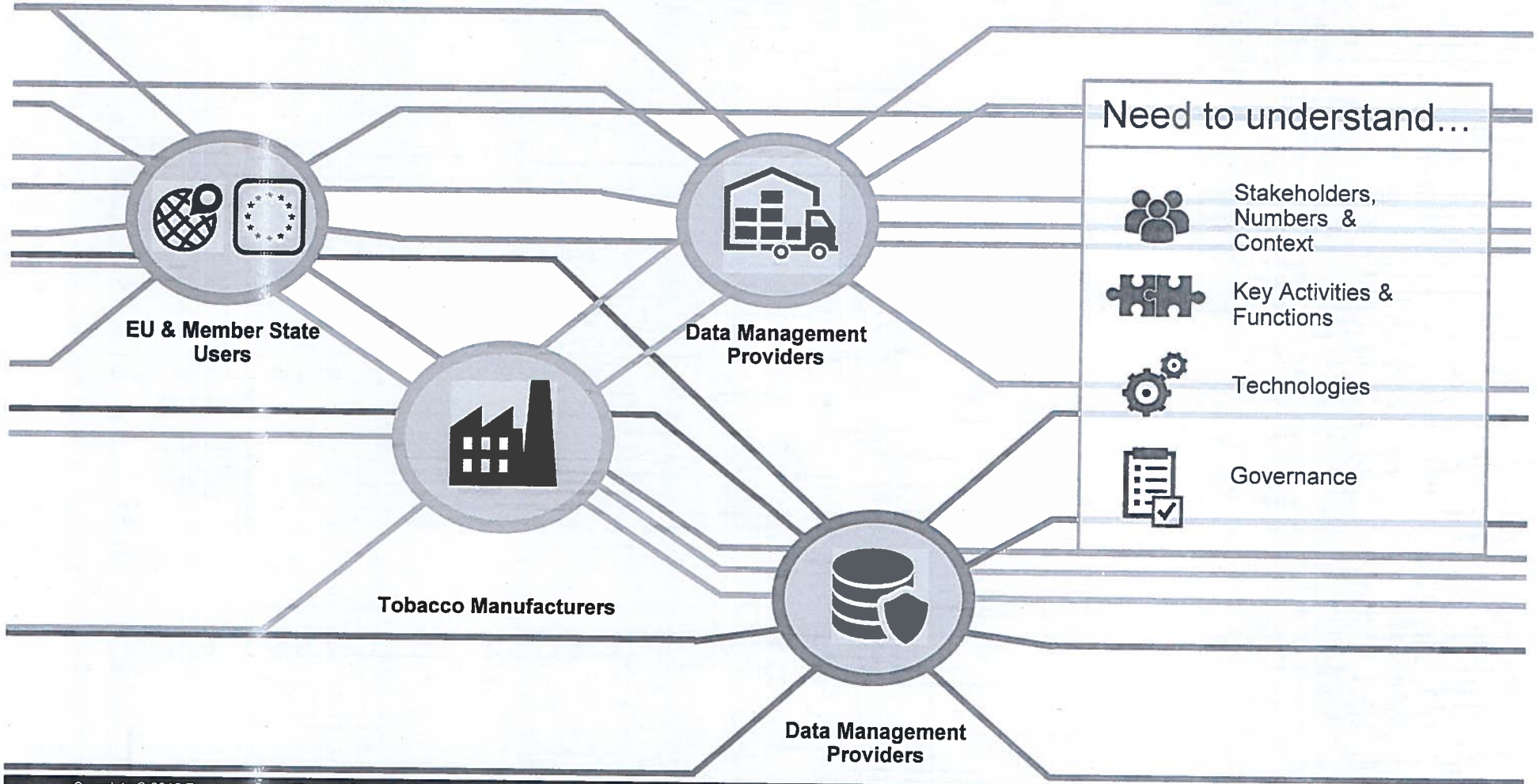
NAVIGATION AID

The Main Actors…



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Tobacco Manufacturing – By the Numbers…

Number of Players & Items in the EU Market…

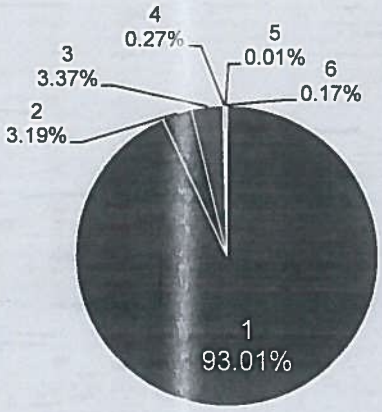
~230 EU Tobacco Enterprises

~745 Cigarette Production Lines in the EU

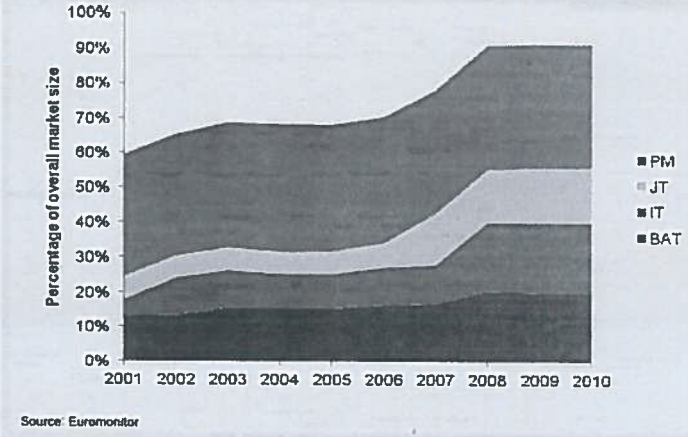
~600 Cigar Finishing Stations in the EU

~30bn Tobacco (All) items per annum in the EU

Cigarettes account for majority of tobacco…

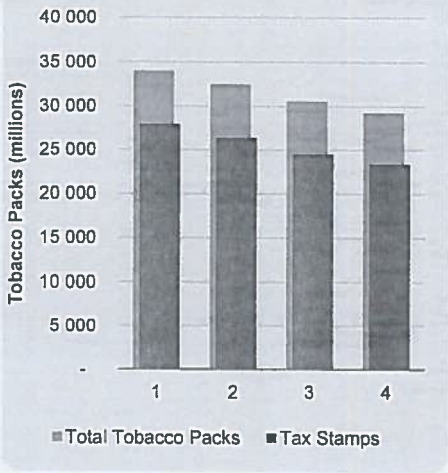


"Big 4" tobacco manufacturers have more than 85% of the overall EU tobacco market…



Source: Euromonitor

Majority of EU Tobacco Products subject to Tax Stamp / Fiscal Marking…



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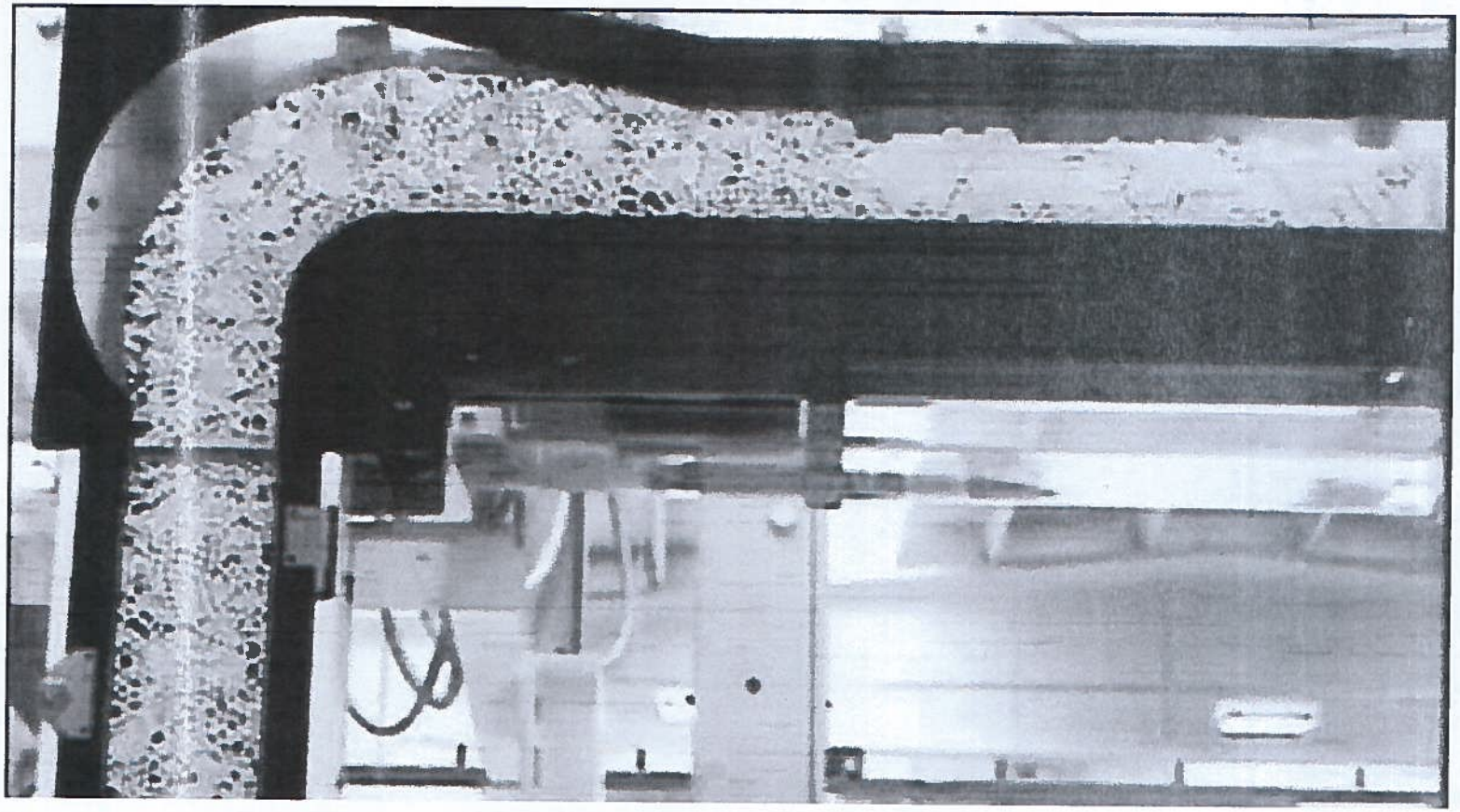
Example: Cigarette Manufacturing



Key Process Steps:

1. Cigarettes into Packs
2. Tax stamp and clear wrap
3. Packs into Cartons
4. Cartons into Mastercases
5. Mastercases into Pallets

Source: http://youtu.be/lPCa1qfiw3I

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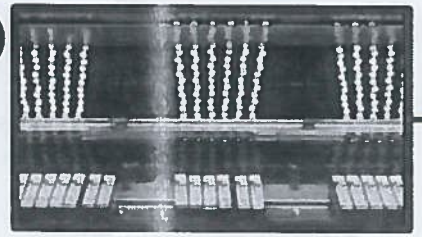
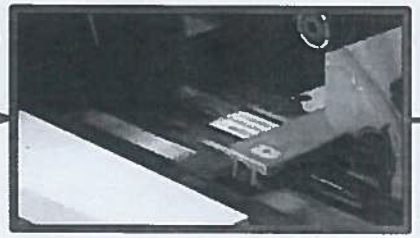
Illustration of Key Solution Components

1 Pack Making Machine



2 Transport of Packs to Wrapping Machine

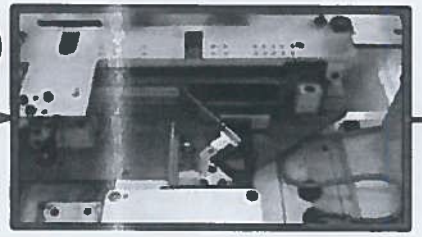


Unique Identifier Generation (Pack) | Printer (Option) | Vision System (Quality) | Label Appli-cator (Option) | Data Record & Submit

3 Wrapping Machine

Placement under overwrap provides protection of Unique Identifier and Security Feature

4 Aggregation: Pack-to-Carton

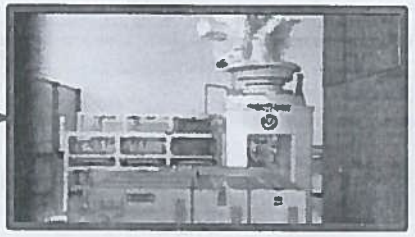


Unique Identifier Generation (Carton) | Printer (Option) | Label Appli-cator (Option) | Vision System (Aggre-gation) | Aggre-gation recording | Data Record & Submit

5 Aggregation: Carton-to-Mastercase

Unique Identifier Generation (Master-case)) | Label Appli-cator (Option) | Vision System (Aggre-gation) | Aggre-gation recording | Data Record & Submit

6 Aggregation: Mastercase-to-Pallet



Unique Identifier Generation (Carton) | Label Appli-cator (Option) | Vision System (Aggre-gation) | Aggre-gation recording | Data Record & Submit

Video Source: http://youtu.be/lPCa1qfiw3I

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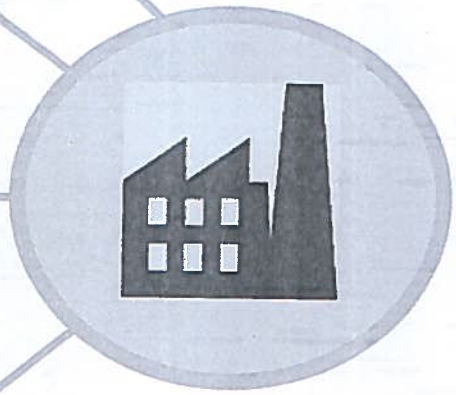
Dashboard: Tobacco Manufacturing

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.

Stakeholders
- Tobacco Manufacturers
- Traceability Solution Providers (where applicable)

Functions
- Serialisation of items, secondary and tertiary packaging
- Recording Aggregation
- Quality management and production verification
- Application of Security Feature requirements (TPD & FCTC)
- Data submission to 3rd party



Technology
- Code Generator to generate unique identifier
- Security Certificate Infrastructure
- Printers (Inkjet, Laser), Inspection (vision) systems), and/or Applicators
- Production line software
- Local Servers (interim storage) & connectivity

Governance
- Framework for traceability oversight
- Access to Manufacturing premises
- Solution provider (where applicable) service level agreements

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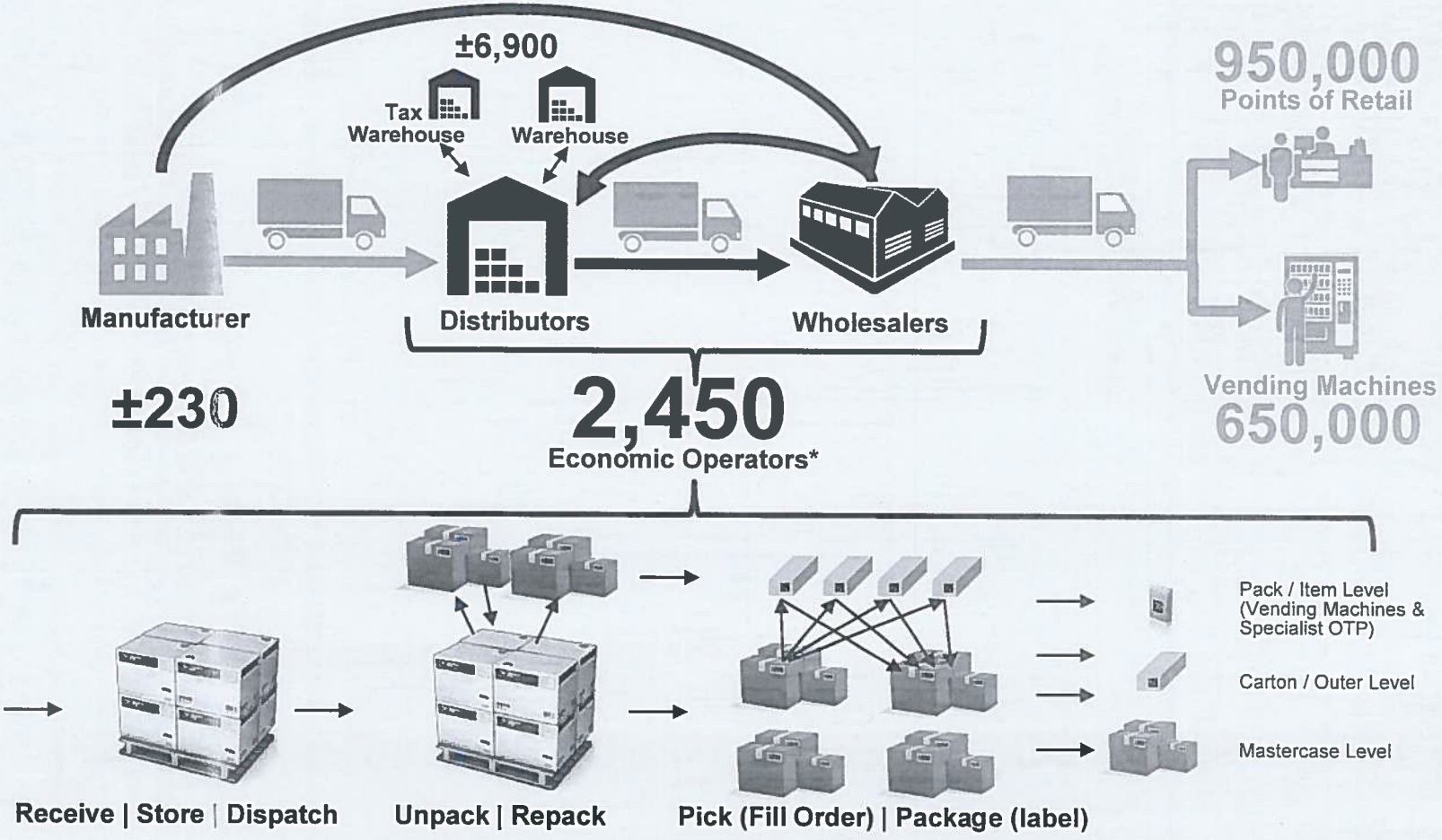
The Distribution Economic Operators



* Source: Eurostat

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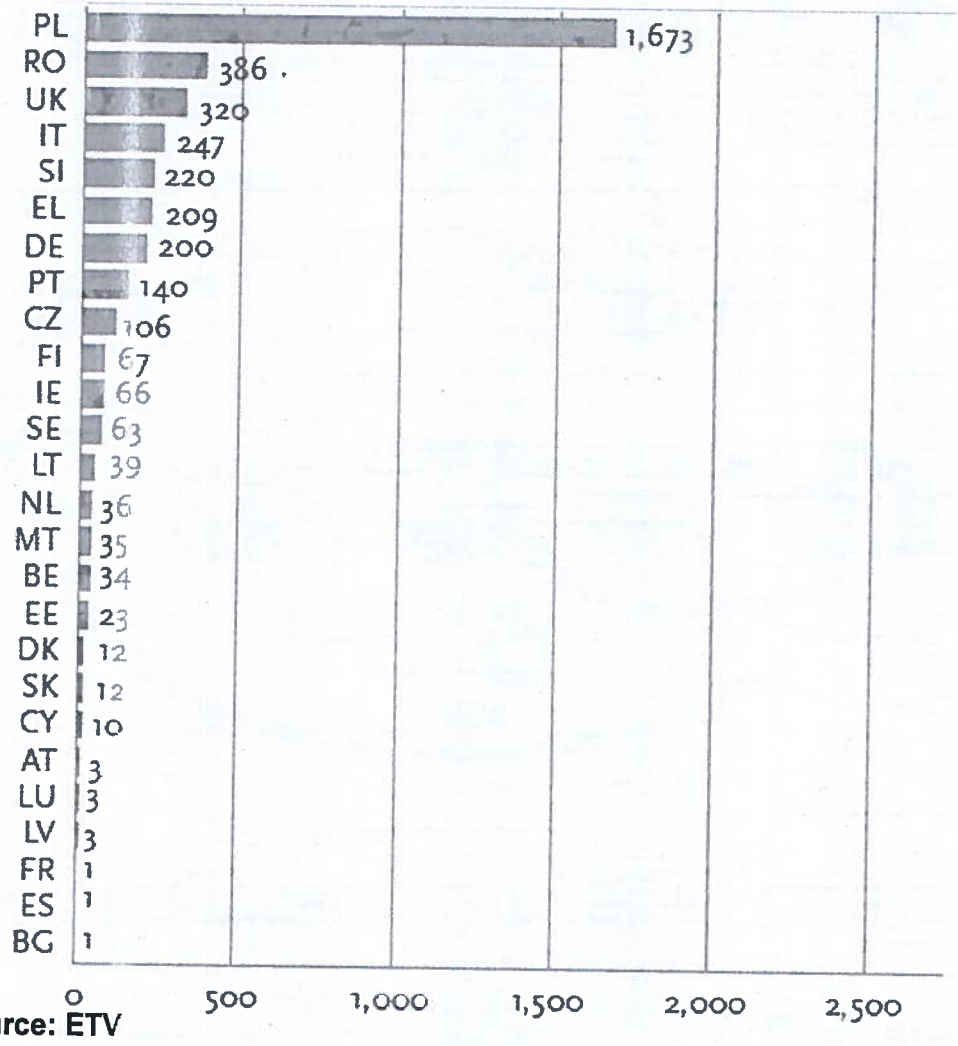
The Distribution Chain Economic Operators



Source: ETV

Large structural variety of Distribution Models across EU:

- Sole Wholesalers (e.g. France, Italy, Spain & Bulgaria)
- Over 1,600 different operators in Poland

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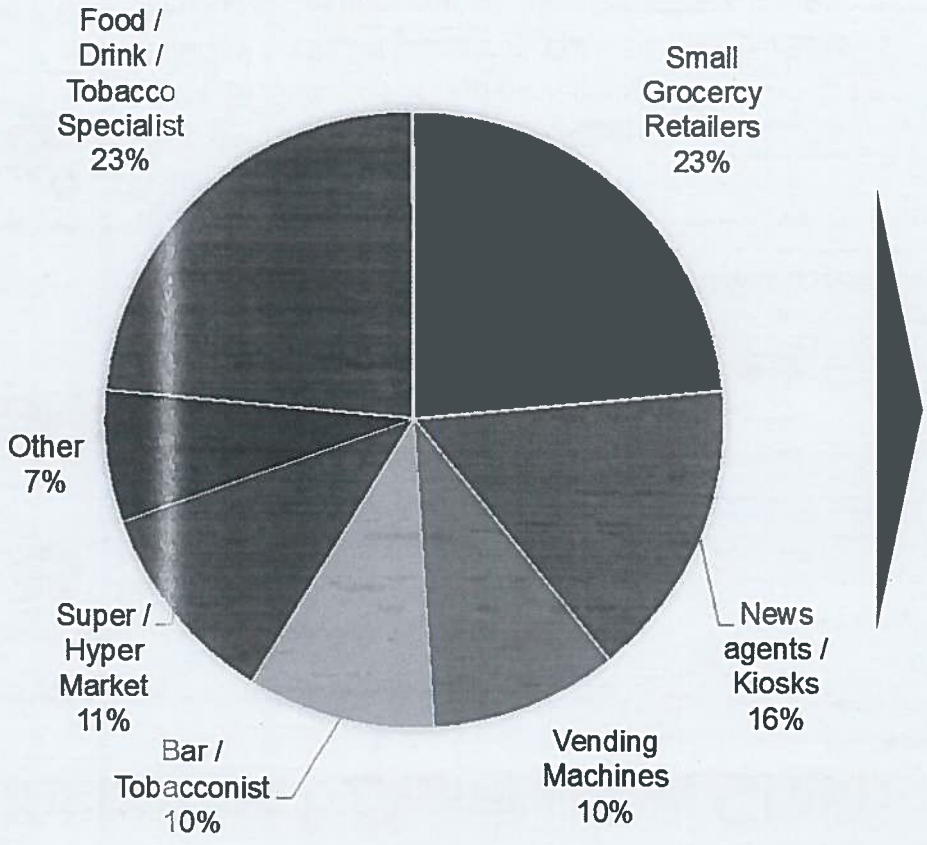
Distribution economic operators supplying variety of retail channels…



Mixed and varied tobacco retail environment requires a mix of wholesaler / distribution supply models:

- Cash & Carry Wholesalers
- Direct / Mobile Sales
- Large Retail Chain distribution networks
- Vending Machine Fulfilment

Source: Economic Analysis of the EU market of tobacco, nicotine and related products, Matrix Insight, 2013

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Dashboard: Distribution Chain

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.

Stakeholders
- Tobacco Manufacturers
- Distribution Chain Operators

Functions
- Logging Events: Change of Custody & Movements
- Scanning Receipt, Repackaging and Dispatch
- Creating new unique serial numbers for packaging (containers)

Technology
- Portable / Handheld Scanning Devices
- Label Printers (re-packaging operations)
- Industry Technical Standards (Data, Carriers & Interfaces)
- Economic Operator system interfaces (ERP & WMS)
- Connectivity to web services for data submission

Governance
- EU / Member State facilitation through Stakeholder working group
- Test environment and assurance processes
- Mechanism for some form of compliance monitoring by EU / MS

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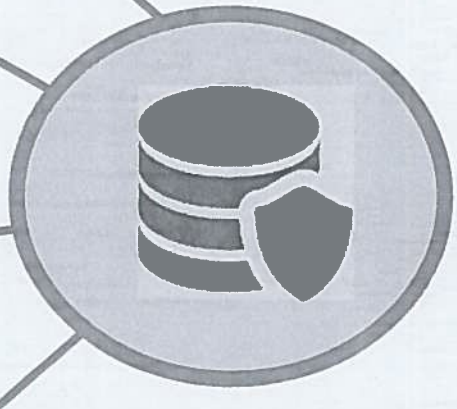
Dashboard: Data Management

Independent storage of all tobacco traceability and related data

Stakeholders
- Data & Application Hosting Service Providers
- Tobacco Manufacturers
- Distribution Chain Actors
- European Commission & Member States Users

Functions
- Data Storage (Hosting)
- Application Hosting (Alerts & Notifications)
- Data Maintenance
- Data Backup
- Disaster Recover / Failover (24/7 Availability)



Technology
- Server and Communications Infrastructure
- Database Software
- Traceability applications & information storage (such as GS1 EPC Information Service)
- Application extensions (e.g. advance shipping notifications, alerts & reporting)

Governance
- Regulations on data storage requirements (EU and MS)
- Approval Mechanism
- Audit Mechanisms

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Dashboard: System Users

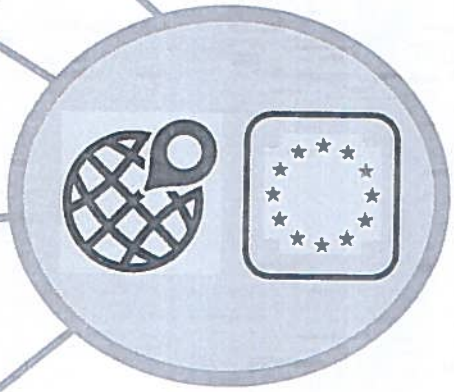
Using the tobacco traceability data to support monitoring, control and enforcement activities by means of simple queries, comprehensive analysis or integration with EU and Member State systems

Stakeholders

- European Commission Users (e.g. Health, Tax OLAF)
- Member State Users (Health, Tax [Policy])
- Law enforcement (Police, Customs, Tax and Public Health)

Functions

- Query Traceability Data
- Dashboards and Oversight
- Reporting (Standard & Custom)
- Alerts & Notifications (e.g. Distribution mismatch, Field Enforcement Results)



Technology

- Business Intelligence Application (Customisation of Commercial Software)
- Data integration services
- User Management
- Service Desk (ideally coupled with data storage)

Governance

- EU Forum for shared BI / Data analysis components
- User activity monitoring and reporting

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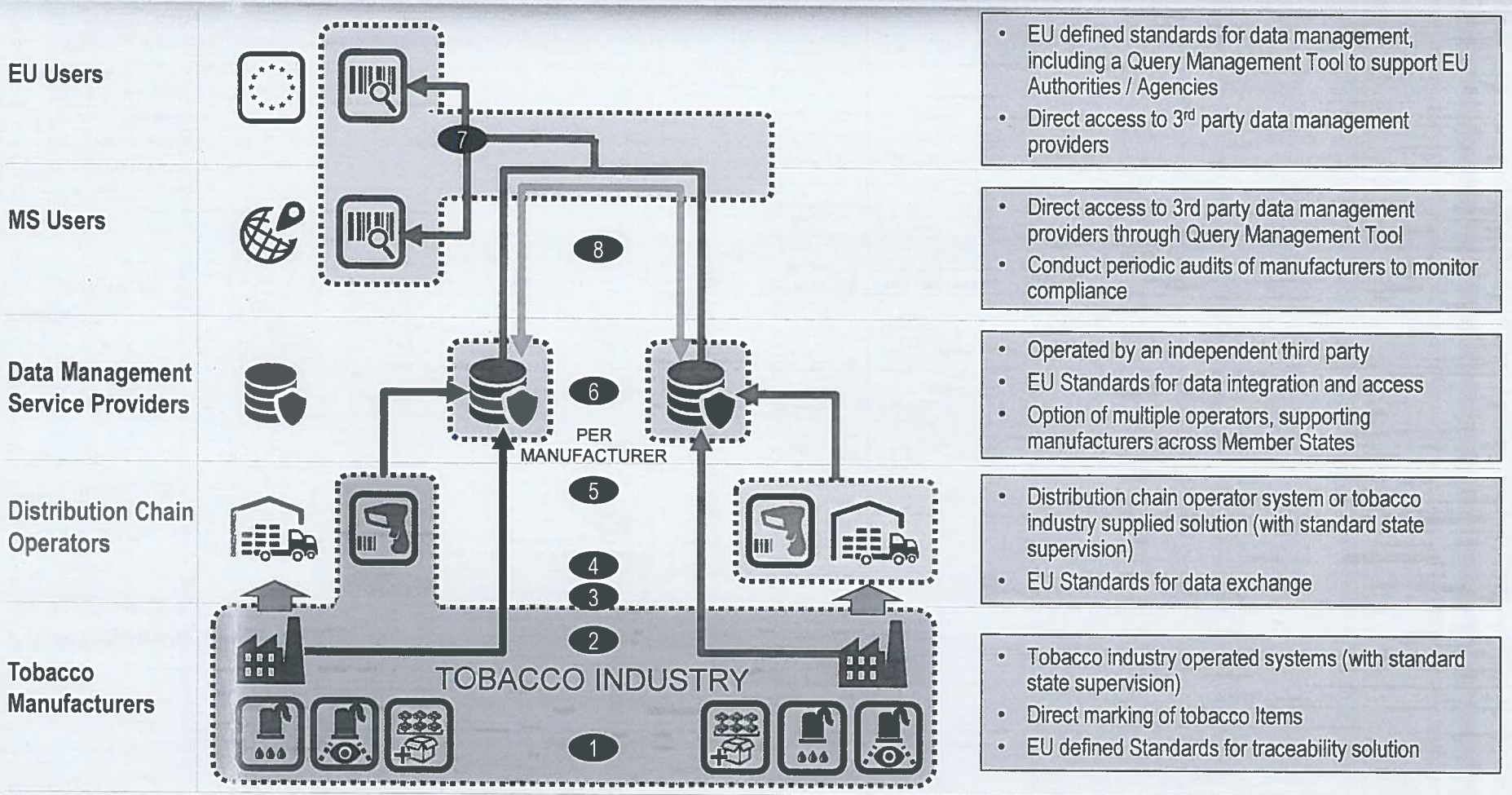
Traceability: Option 1



- EU defined standards for data management, including a Query Management Tool to support EU Authorities / Agencies
- Direct access to 3rd party data management providers

- Direct access to 3rd party data management providers through Query Management Tool
- Conduct periodic audits of manufacturers to monitor compliance

- Operated by an independent third party
- EU Standards for data integration and access
- Option of multiple operators, supporting manufacturers across Member States

- Distribution chain operator system or tobacco industry supplied solution (with standard state supervision)
- EU Standards for data exchange

- Tobacco industry operated systems (with standard state supervision)
- Direct marking of tobacco Items
- EU defined Standards for traceability solution

1. Manufacturer applies direct marking on packs, verifies it and ensures aggregation (with standard state supervision)
2. Manufacturer uploads data to 3rd party Data Management Service Provider in an agreed form
3. Product moves to Distribution Chain Operators
4. Distribution Chain Operators scan and record event either using own systems (with standard state supervision) or tobacco manufacturer provided system
5. Distribution Chain Operator uploads data to 3rd party Data Management Service Provider in agreed format
6. Data Management providers store and make available traceability data to authorities
7. Member States and EU Agencies access traceability data via Query Management Tool / Interface
8. Query system includes a discovery service to support traceability queries accessing data across multiple independent databases

Printer
Query Tool
Vision System
Data Store
Scanner
Aggregation Recording

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Traceability: Option 2

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EU Users

- EU prescription of standards, Track and Trace solution architecture, and its operation
- One harmonised system across the EU
- Direct access to 3rd party data management providers through Query Tool / Interface

MS Users

- Direct access to 3rd party data management providers through Query Tool or Interface
- Member State traceability data may be replicated territorially
- Responsible for compliance management enforced by Member State legal provisions

Data Management Service Providers

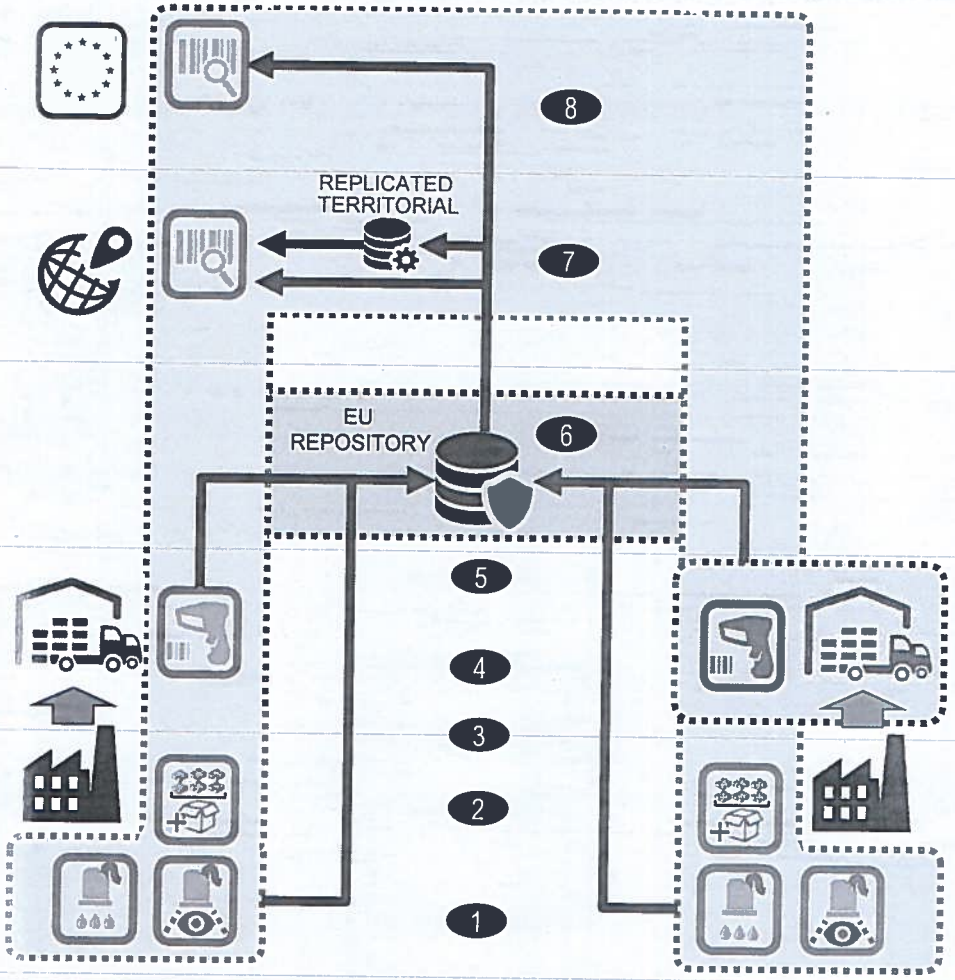
- Operated by an independent third party
- Primary EU data repository (with option to be replicated territorially for Member States)
- EU standards for data integration and access
- EU standards for access

Distribution Chain Operators

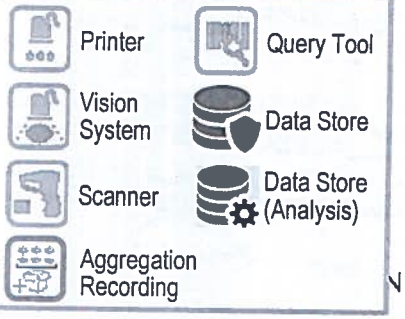
- Distributors comply with agreed standards as per EU harmonised solution
- Distributors either: use own systems adopting published standard for automated data exchange; or use system offered by solution provider

Tobacco Manufacturers

- EU prescribed standards for a single solution for tobacco traceability
- Solution provider provides equipment implemented on manufacturing lines
- Controlled and maintained by one or more providers independent of tobacco industry



1. Solution provider(s),(independent of tobacco Industry) implements unique identifier generation, marking and aggregation (Item-to-carton/outer, carton/outer-to-mastercase and mastercase-to-pallet) according to EU standards Solution providers upload data to 3rd party Data Management Service Provider
2. Product moves to Distribution Chain Operators
3. Distribution Chain Operators scan and record event either: using own systems (with standard state supervision) or service provider solution(s)
4. Distribution chain data is uploaded using agreed standards for exchange
5. Independent Data Management providers store & make available traceability data to support queries by authorities
6. Member States access data via Solution Provider Query Tool / Interface
7. EU accesses traceability data via Solution provider Query Tool / Interface



Traceability: Option 3a

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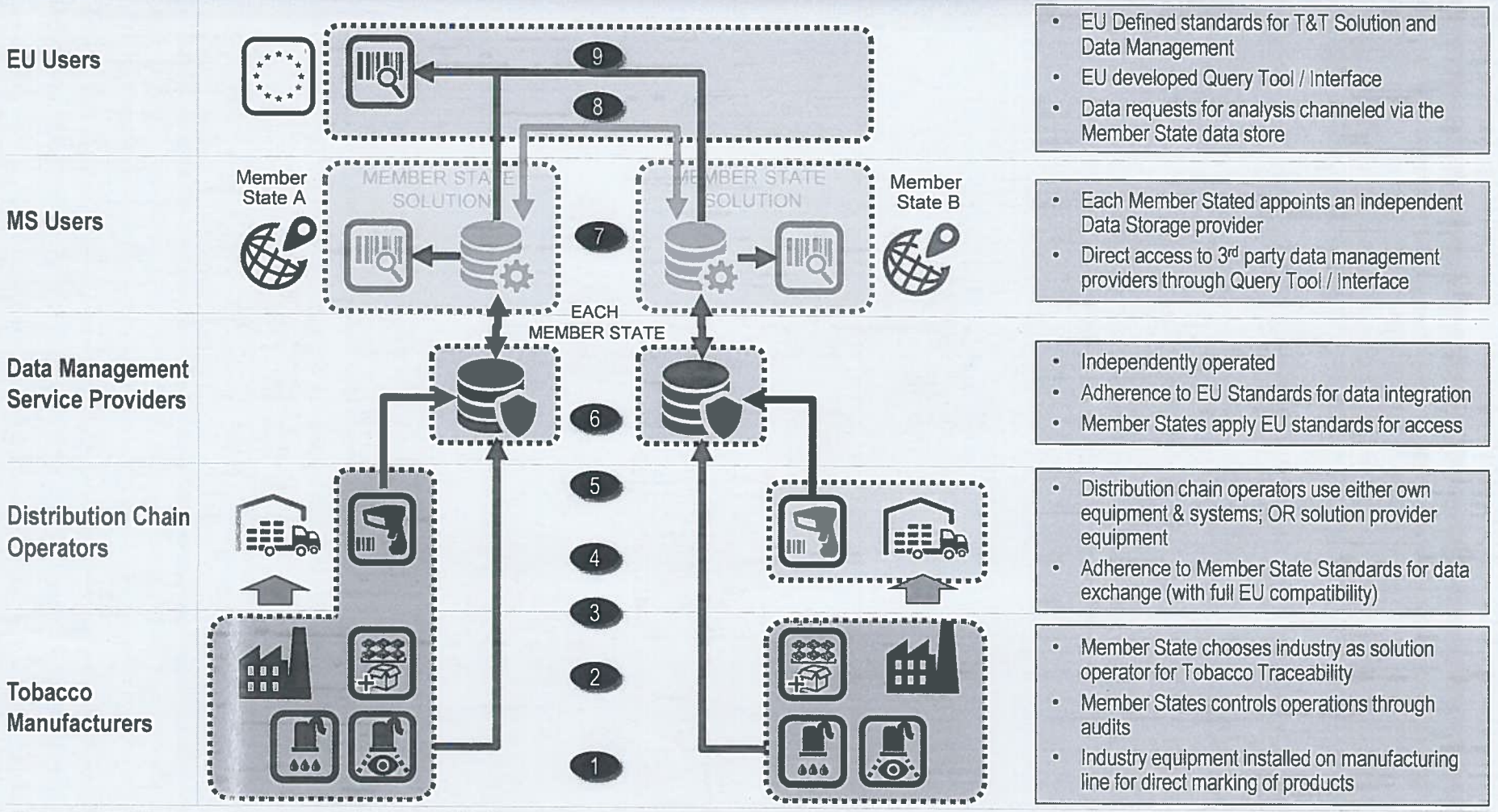
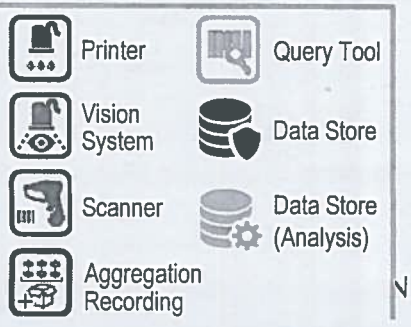


1. Member State chooses tobacco industry solution, with industry applying direct marks, ensuring verification and aggregation on tobacco manufacturing line (as in option 1)
2. Industry uploads data to independent 3rd party Data Management Service Provider
3. Product moves to Distribution Chain Operators
4. Distribution chain operators scan and record events, upload data to independent 3rd party Data Management Service Provider in an agreed form.
5. Distribution chain data is uploaded using agreed standards for exchange
6. Independent Data Management providers store & make available traceability data for Member State Queries
7. Member States access traceability data via a Member State Query Management Tool
8. EU Query service enables queries that require accessing data across multiple Member State data repositories
9. EU accesses traceability data via Member State Query Management Tool



Traceability: Option 3b

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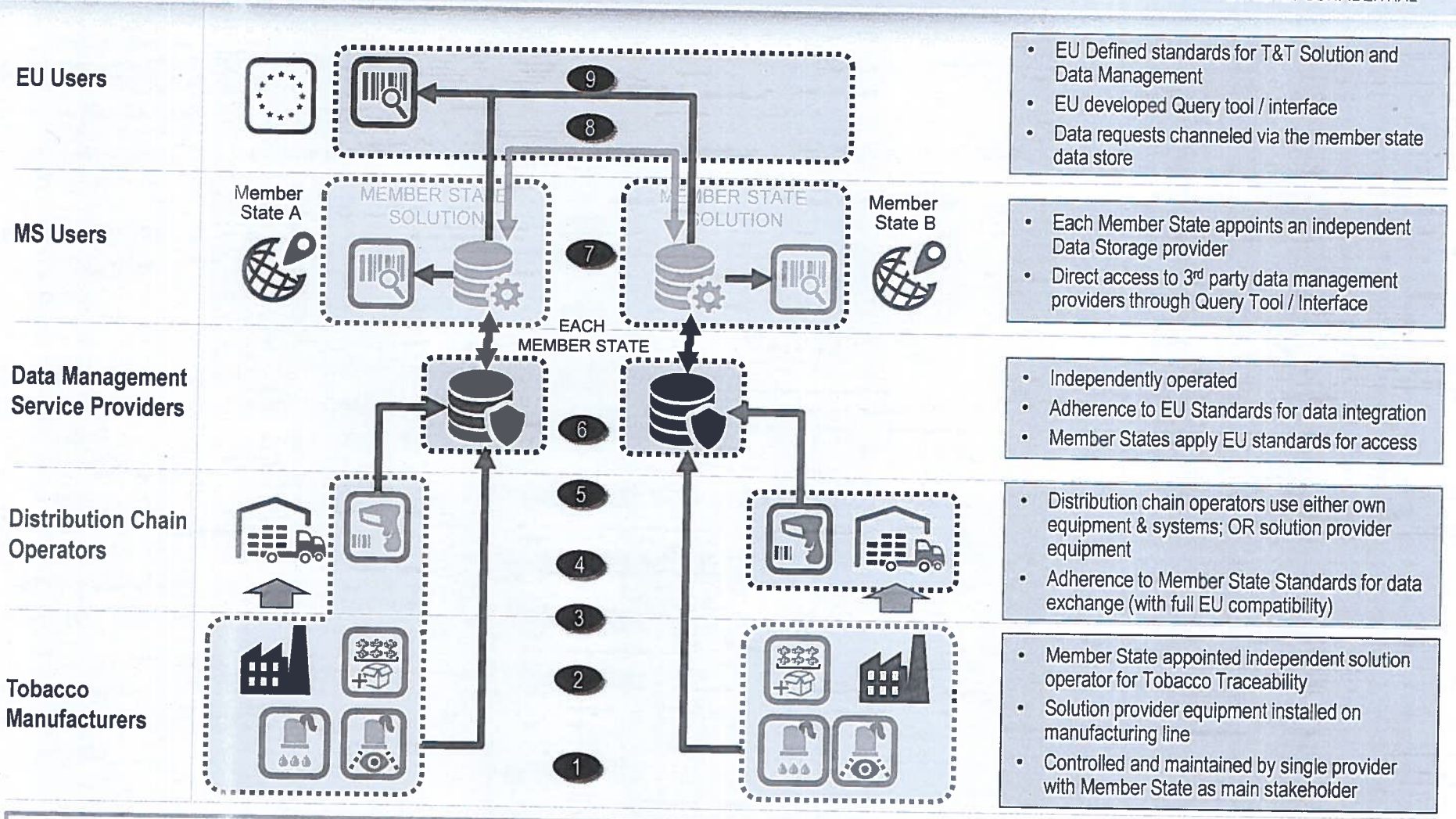


- EU Defined standards for T&T Solution and Data Management
- EU developed Query tool / interface
- Data requests channeled via the member state data store

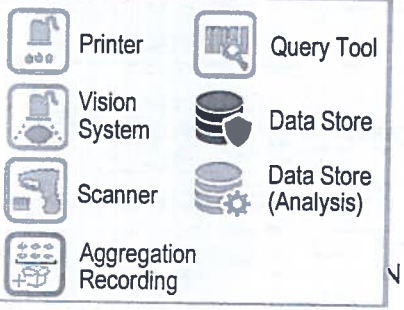
- Each Member State appoints an independent Data Storage provider
- Direct access to 3rd party data management providers through Query Tool / Interface

- Independently operated
- Adherence to EU Standards for data integration
- Member States apply EU standards for access

- Distribution chain operators use either own equipment & systems; OR solution provider equipment
- Adherence to Member State Standards for data exchange (with full EU compatibility)

- Member State appointed independent solution operator for Tobacco Traceability
- Solution provider equipment installed on manufacturing line
- Controlled and maintained by single provider with Member State as main stakeholder

1. Member state appointed independent solution provider direct marks, QC & oversight of aggregation (Item-to-carton/outer, carton/outer-to-mastercase and mastercase-to-pallet) on manufacturing line (as per option 2)
2. Solution provider uploads data to 3rd party Data Management Service Provider
3. Product moves to Distribution Chain Operators
4. Distribution chain operators scans and records event using own industry solutions
5. Independent Service Provider solution uploads data for Member State control
6. Independent Data Management providers store & make available traceability data
7. Member States accesses data via Independent Solution Provider Query Management Tool
8. EU Query service enables queries that require accessing data across multiple Member State data repositories
9. EU accesses traceability data via Member State Independent Solution provider Query Management tool



Traceability: Option 4

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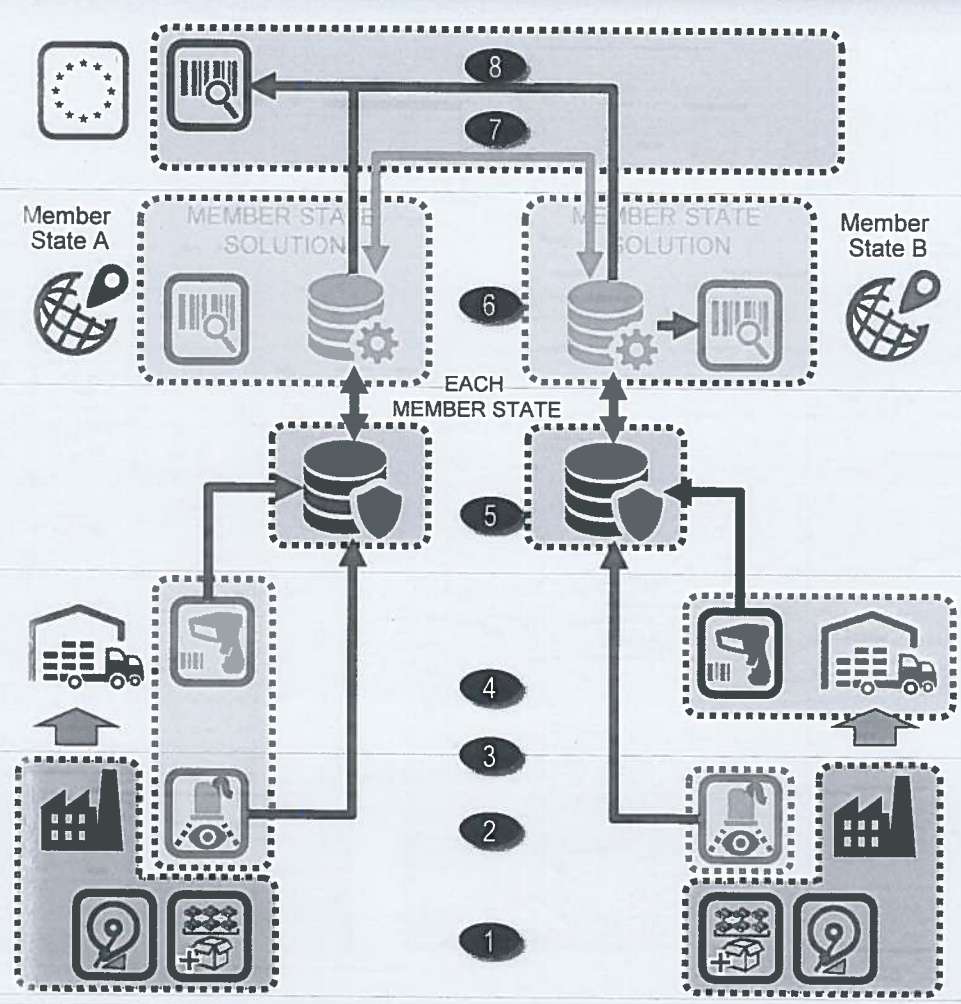


- EU Defined standards for Traceability Solution, Data Management, and Security Features (SF)
- EU developed Query Management tool / Interface
- Data requests channeled via the member state data store

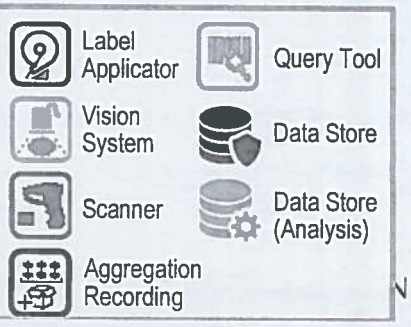
- Member State uses combined Security Feature and Tobacco Traceability T&T solution
- Direct Access to 3rd part data stores for query management

- Independently operated
- Adherence to EU Standards for data exchange
- Member States apply EU standards for access

- Distribution chain operators use either own equipment or solution provider equipment
- Adherence to Member State Standards for data exchange (with full EU compatibility)

- Member States choose solution provider for Tobacco Traceability and Security Feature
- Security Feature (with Unique Identifier code) is applied by manufacturers and verified by solution provider's vision equipment on manufacturing line

1. Member State chooses independent solution provider for Security Feature (containing unique identifier). Tobacco manufacturer responsible for application of security feature and recording of aggregation events (Item-to-carton/outer, carton/outer-to-mastercase and mastercase-to-pallet)
2. Solution Provider (independent of manufacturer) records application of security feature and each unique identifier & uploads data to 3rd party Data Management Service Provider (as far as Security Feature and Unique Identifiers concerned)
3. Product moves to Distribution Chain Operators
4. Distribution chain operators scan & record events using either own equipment or solution provider & upload to independent data provider
5. Independent Data Storage providers store & make available traceability and SF data
6. Member States access traceability and SF data via Query Tool / Data interface
7. EU Query service enables queries that require accessing data across multiple Member State data repositories
8. EU accesses traceability and Security Feature data via Member States Query tool / Interface`



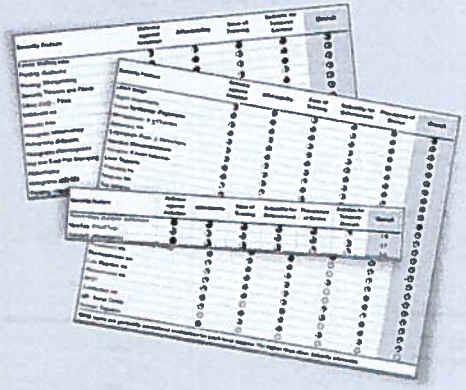
Proposal of Four Security Feature Options

Requirements

- TPD Article 16
  - Tamperproof Security Feature
  - Visible and Invisible
  - Irremovable printed or affixed
  - Not hidden or interrupted
  - Choice for MS to combine with Tax Stamp with provision
- ISO 12931:2012(E) distinction:
  - Overt
  - Covert
  - Forensic

Technologies & Options available

- Many choices from realms of security printers (currency, value documents) and brand protection providers
- Multitude of specific proprietary components – but flexibility to combine and mix



Four options…

Key Considerations:

- Already in operation; or
- New and emerging
- Cost effective
- Fit for tobacco domain
- Basis for a standard that enables market competition across EU

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Summary of Security Feature Options

Article 16 Security feature to tackle illicit products has a similarity with tax stamp:

- Provide Authentication
- Resistat duplication / counterfeiting
- Suitable for Tobacco Domain

Example of Security elements on a Modern Tax Stamp:

- Tax Stamp Technical Study (2012) by Reconaissance Int'l cites a modern tax stamp
- Kenya Tax Revenue Authority

Option 1 – Similar to Tax Stamp	
Level 1 (Overt)	Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature (1A) or Semi-covert Ink Effect (1B)
Level 3 (Covert)	Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

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Summary of Security Feature Options

- Traceability and unique identifier provides a verification elements (albeit weak).
- Therefore – consideration of a security feature with reduced semi-covert elements
- Still contains overt authentication elements (for consumers) and covert & forensic elements

Option 2 – Reduced Covert (semi-covert)	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink (Optional) Iridescent ink or foil
Level 2 (Semi-Covert)	Rely on Track and Trace Serialisation (separate from security feature)
Level 3 (Covert)	Laser or Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker (DNA, Chemical or Nano)
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

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Summary of Security Feature Options

Exploration of implications of incorporating an emerging fingerprinting technology

Option 3 – Addition of Material Fingerprinting	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink
Level 2 (Semi-Covert)	Fingerprinting Technology
Level 3 (Covert)	Fingerprinting Technology
Level 4 (Forensic)	Forensic Marker (DNA, Chemical or Nano)
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

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Summary of Security Feature Options

Uses the base security feature (option 1) + includes the Unique Identifier (for traceability option 4)

Option 4 – Includes Unique Machine Readable Code	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature or Semi-covert Ink Effect
Level 3 (Covert)	Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences
Variable Data	Inclusion of unique identifier

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Four Security Feature Options

Option 1 – Similar to Tax Stamp	
Level 1 (Overt)	Optically Variable Device (Option 1A) or Optically Variable Ink (Option 1B) Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature (1A) or Semi-covert Ink Effect (1B)
Level 3 (Covert)	Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 2 – Reduced Covert (semi-covert)	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink (Optional) Iridescent ink or foil
Level 2 (Semi-Covert)	Rely on Track and Trace Serialisation (separate from security feature) (Optional) Micro-particles
Level 3 (Covert)	Laser or Machine Readable Taggant
Level 4 (Forensic)	Forensic Marker (DNA, Chemical or Nano)
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
Paper	Frangible paper, tax stamp quality suitable for use in high speed label applicators (dry labels)
Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 3 – Addition of Material Fingerprinting	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink
Level 2 (Semi-Covert)	Fingerprinting Technology
Level 3 (Covert)	Fingerprinting Technology
Level 4 (Forensic)	Forensic Marker (DNA, Chemical or Nano)
Tamper-proof	Frangible Paper and adhesive Die cuts (Kiss cuts) for self-adhesive labels
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Application Method	Dry Label and Self Adhesive label Available as stacks or reels to suit manufacturers preferences

Option 4 – Includes Unique Machine Readable Code	
Level 1 (Overt)	Optically Variable Device or Optically Variable Ink Overt Guilloche Pattern
Level 2 (Semi-Covert)	Micro text UV inks with bi-fluorescence reaction Covert Holographic Feature or Semi-covert Ink Effect
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Agenda

1 Background & Context

- Project Status
- Deliverables & Tasks
- Constraints & Challenges
- Key Stakeholders
- Baseline for Analyses (Problem Statement)
- Relevant Benchmarks & Trends

2 Key Concepts & Methodology

- Traceability: Key concepts
- Security Features & Authentication: Key Concepts
- Project Methodology
- Stakeholder Engagements

3 Four Options Defined

- Overview of a Traceability Solution
- Description of the Four Traceability Solution Options
- Description of the Four Security Feature Options

4 Analyses and Outcomes

- Implications and Requirements
- Feasibility Concerns
- Additional Solution Considerations
- Cost Benefit Analyses
- Conclusions and Recommendations

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of the European Union

European Commission

Provision of an Analysis and Feasibility Assessment regarding EU Systems for Tracking and Tracing of Tobacco Products and for Security Features

Executive Summary and Member State Briefing (Part 4)

December 2014

Call for tender No EAHC/2013/Health/11
2013/S 068-112544

SOVEREIGN BORDER SOLUTIONS

EUROGROUP CONSULTING

These presentation materials were prepared for the 1st meeting of the Sub-Group on Traceability and Security Features of the expert group on Tobacco Policy, and presented on 10 December 2014.

The materials are based on a substantive (+300 pages) draft report, still subject to finalisation and approval by the EU Commission. The slides were prepared for illustrative purposes, and represents only a partial representation of the meeting discussions and presentations.

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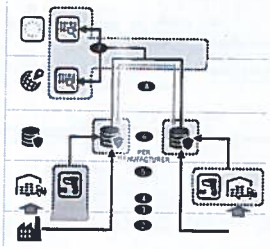
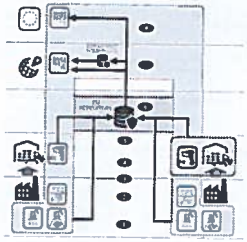
Recap: Four Traceability Options

Option 1



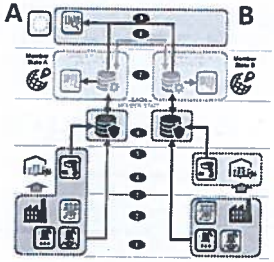
Solution(s) is/are operated by each tobacco manufacturer, and each proposing own data repository.

Option 2



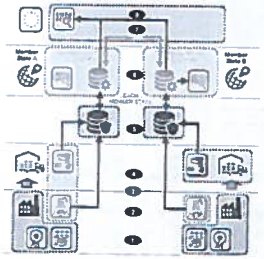
Solution is provided and operated by independent solution provider(s), with a single EU-wide data repository

Option 3



Each Member States selects a Solution provider and data management provider (at national level). Could be industry or not.

Option 4



Integrated security feature solution with on-production-line application recording by independent solution provider(s), determined by each Member State

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NAVIGATION AID

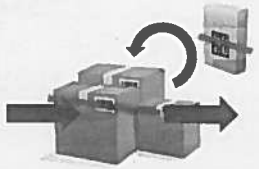
Overview of a Traceability Solution

Tobacco Manufacturing Facilities

- Serialisation of tobacco items marked with a unique identifier
- Production verification
- Security feature
- Aggregation

Distribution Economic Operators

- Distribution Events up to the last economic operators before first point of retail



Data Storage Providers

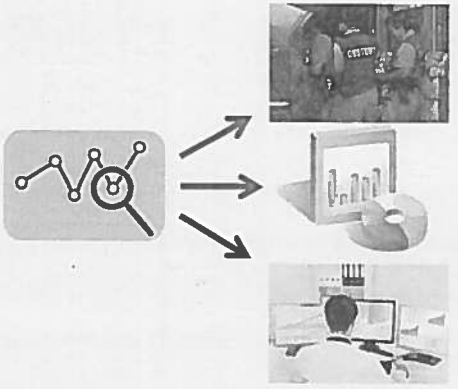
- Independent storage of traceability data

Member State Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with Member State systems

European Union Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with EU systems



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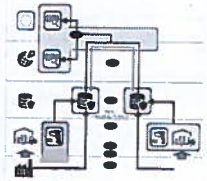
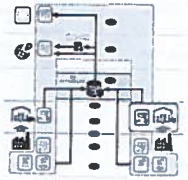
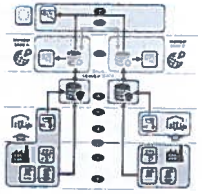
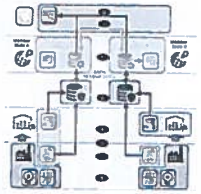
Assessment
Serialisation and Production Verification

	Option 1	Option 2	Option 3	Option 4
				
Unique Identifier generated by	Manufacturer	Service Provider	Combination of Option 1 and 2	Security Printer
Serialisation equipment procured & maintained by	Manufacturer	Service Provider	Combination of Option 1 and 2	Application: Mnf Vision System: SP
	Printed / Marked directly onto tobacco item (inkjet / laser)			Integrated into security feature (label)
Identifier – Unique & Non-Pred & Encrypted	Unique Identifier Generation (Pack)			
Compatibility & Interoperability		On-Line Printer		
Quality Control			Vision System (Quality)	Label Applicator Vision System (Recording)

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Assessment:
Data Elements forming "Part of" the Unique Identifier

Feasibility Consideration: Technical constraints and current business processes (what is known at time of manufacture) may impact information that forms part of the unique identifier (i.e. accessible without an online link to a database)

WHO FCTC Protocol	TPD – Article 15
11 Data Elements -- **4** included as part of unique identifier	**11** similar data Elements -- **8** included as part of unique identifier

Unique Identifier – 8 Elements in total

FCTC & TPD	+	TPD
Date and location of manufacture		Machine used to manufacture the tobacco products
Manufacturing facility		Production shift or time of manufacture
The intended market of retail sale		Intended shipment route
Product description		Importer into the Union

Concerns & Options

- Comparison: current serialisation solutions use unique identifier size of 12-20 characters. Estimate for TPD may require 4-5 times that size
- Technical constraints pressure on reducing size of the unique identifier
- Possibility to use database link or EAN / UPC retail barcode as data source as far as possible

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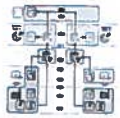
Assessment: Aggregation of Tobacco Items

	Option 1	Option 2	Option 3	Option 4
				
Aggregation data recorded by:	Manufacturer	Service Provider	Combination of Option 1 and 2	Manufacturer
Common across all four options:	• Unique serial number generated for each carton / outer / bundle • Mechanism to ensure unique across production line, manufacturer, EU Member State (and globally) • Compatibility and interoperability • Quality control vision system on the production line to ensure readability (quality) of the applied unique identifiers			
Technical Solution Components	Unique Identifier Generation (Carton /Outer)	Printer (Option)	Label Appli-cator (Option)	Vision System (Aggregation)	Aggre-gation recording	Data Store & submit

Feasibility considerations

- Requires flexibility in positioning of labels and unique identifiers recommended

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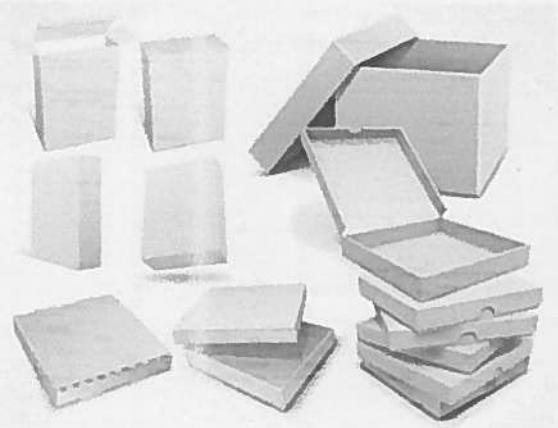
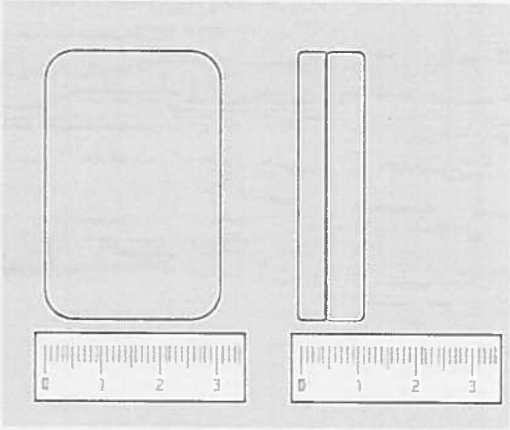
Assessment:
SME Manufacturers & Other Tobacco Products

Feasibility Concern: Accommodating nature of OTP and Small manufacturers business processes may require flexibility in method for application of unique identifiers and security features.



Example: Broad variety of packaging types associated with tobacco products

Distinction between manufacture and finishing: Health warnings and retail barcodes on (self-adhesive reels) applied at time of order only



Small product packages illustrate benefits of potential combination of unique identifier, security feature and self-adhesive label

Small Manufacturers

- Lower levels of automation
- Multiple small batch runs
- Low volume / niche OTP
- Many low-speed stations
- Produce and then finish on order receipt
- Packaging variation

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Assessment:
SME Producers & Other Tobacco Products

Feasibility Consideration: Nature of OTP and Small manufacturers business processes and structures may have practical and high cost implications on direct product marking method of option 1, 2 and 3.

Option 1 - 3

Option 4

Solution Components

- High speed direct marking poor fit with very low volume / low levels of automation production lines.
- Alternative of using label printers for each line – but still requires code generation infrastructure for each line
- Quality control mechanism may require handheld scanners for each finishing station

- Security feature available as either dry label or self-adhesive label (low impact)
- Unique identifier activation of finished product using a handheld device

Implementation Consideration:

- Enabling application of unique identifier by means of label (self-adhesive) applied to the tobacco item – providing support for variety of packaging materials: packs, tins, tubes, boxes (wood, metal & plastic), pouches
- Unique identifier application at time of "finishing" rather than "manufacture" – applying final packaging elements ready for sale (application of health warnings, retail barcodes (EAN / UPC) and tax stamps.

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NAVIGATION AID

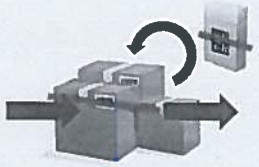
Overview of a Traceability Solution

Tobacco Manufacturing Facilities

- Serialisation of tobacco items marked with a unique identifier
- Production verification
- Security feature
- Aggregation

Distribution Economic Operators

- Distribution Events up to the last economic operators before first point of retail



Data Storage Providers

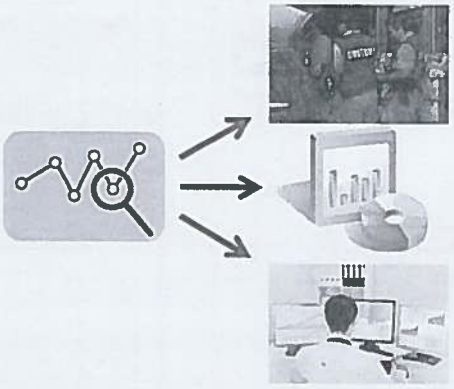
- Independent storage of traceability data

Member State Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with Member State systems

European Union Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with EU systems



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Assessment
Distribution Chain Operators

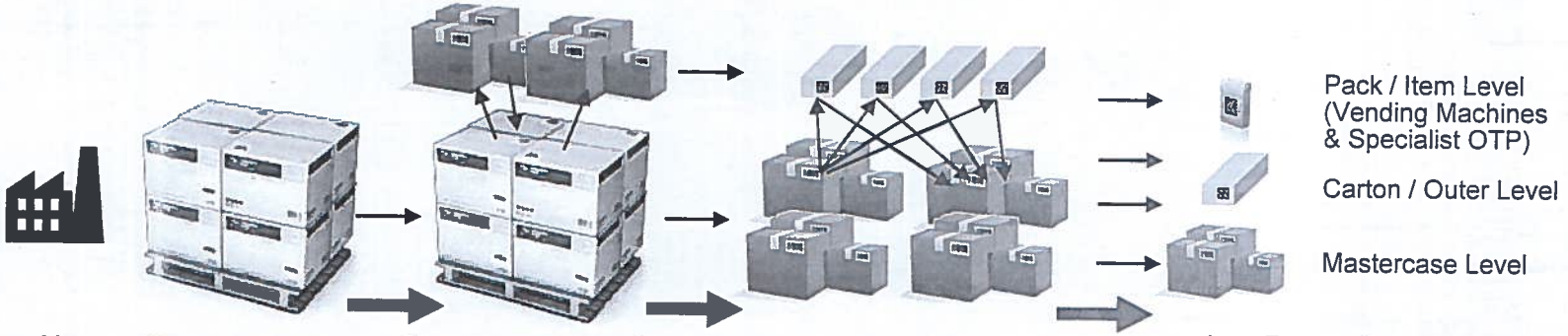
Key considerations

- Scanning on receipt / dispatch
- Impact of unpacking and repacking operations (and relabeling)
  - Pallet and Master case level at early stages
  - Further along –mastercases, cartons / outers, and down to unit level
- Registration with body such as GS1 for unique location number & packaging unique identifiers
- Reverse logistics (even though low volume)

Anticipated High Impact:

Direct (mobile) Sales	• Mobile scanning devices per mobile team member • Sales recorded down to unit level
Vending Machines	
"Cash" Wholesalers	• Point of Sale upgrade to record unique identifier and Customer details

Increasing Disaggregation and Re-Aggregation at lower granularity through Distribution Chain



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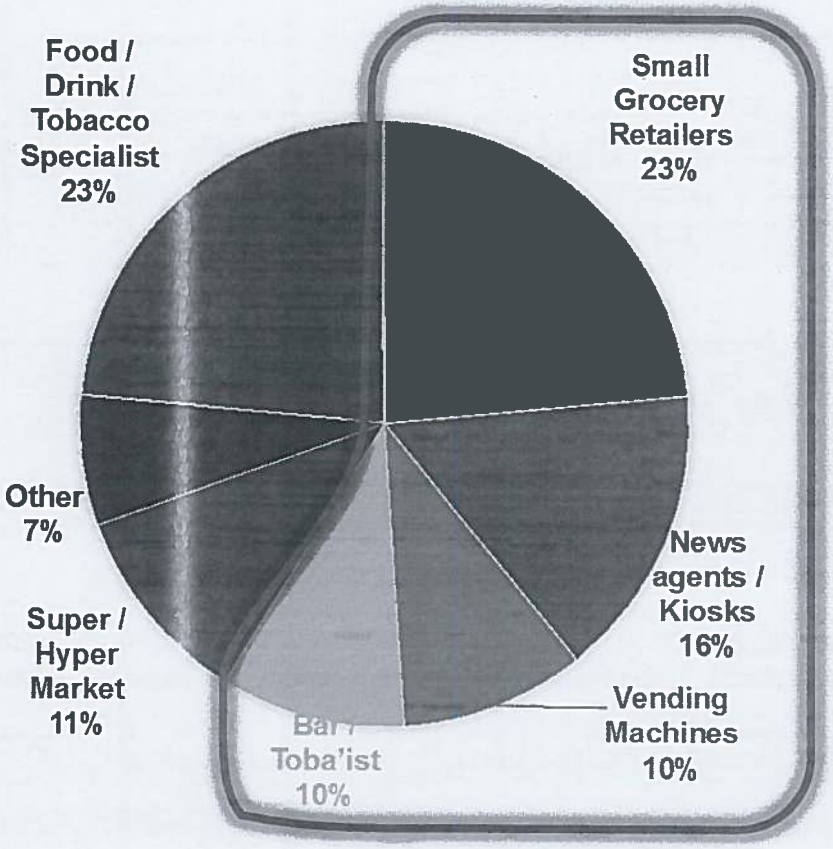
Assessment:
Distribution economic operators supplying variety of retail channels

Feasibility Consideration:
Large portion of the EU tobacco market is supplied by distribution chain operators that are likely to be significantly impacted



Over 50% of tobacco sales channels likely to require supply at sub mastercase levels

- Cash & Carry Wholesalers
- Vending Machine Sales
- Direct / Mobile Sales

Source: Economic Analysis of the EU market of tobacco, nicotine and related products, Matrix Insight, 2013

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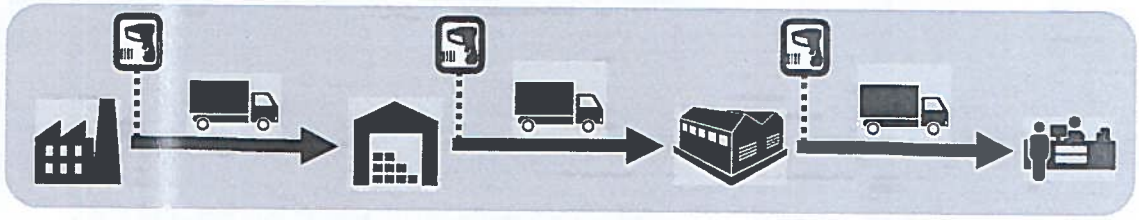
Assessment:
Considering Granularity of Traceability Events

Varying degrees at which distribution chain events Tobacco traceability events are collected. A model based on dispatch and receipt events by facilities optimises information collected with distribution chain overhead.

A

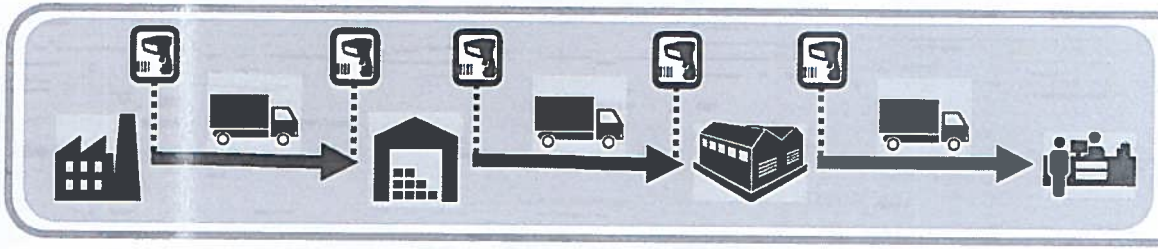


3 Scanning Events

Data that can be determined:

- ✓ Who is next Customer
- ✓ Who is Transporter
- ✗ Duration of Transport
- ✗ Products in Transport or in Storage
- ✗ Discrepancy Alert

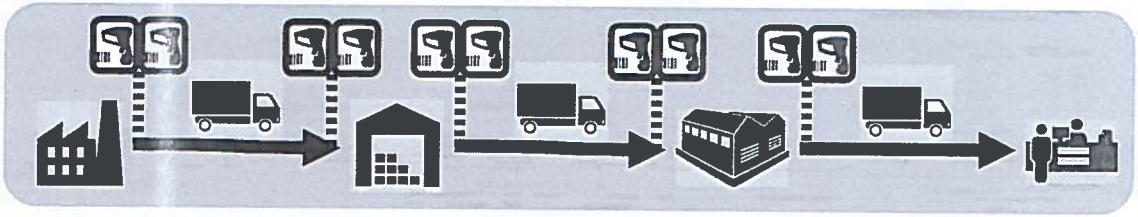
B



5 Scanning Events

- ✓ Who is Next Customer
- ✓ Who is Transporter
- ✓ Duration of Transport
- ✓ Products in Transport or in Storage
- ✓ Discrepancy Alert

C



10 Scanning Events

- ✓ Who is Next Customer
- ✓ Who is Transporter
- ✓ Duration of Transport
- ✓ Products in Transport or in Storage
- ✓ Discrepancy Alert

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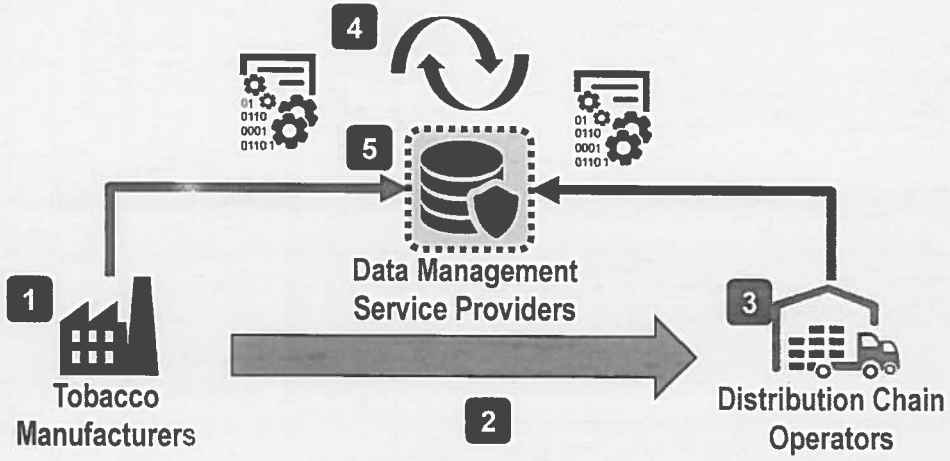
Assessment: Regulating Compliance in the Supply Chain

Across all four traceability options

- Discrepancies, mistakes and clerical errors are a reality
- The decision points - to what degree will stakeholders be responsible to address?
  - Thresholds to allow some flexibility
  - Different response possibilities: periodic audit by MS, notifications to stakeholders or forced reconciliation
- Balancing control with burden on stakeholders – opportunity for progressive implementation

Example of Self-Reconciliation Model



1	Manufacturer captures and uploads track and trace data and dispatches goods
2	Tobacco products are transported to customer (Distribution Chain Operators
3	Upon receipt, distribution chain operator (DCO) scans goods and uploads data
4	At this point an initial check is conducted to ensure that data uploaded by manufacturer is corroborated by actual goods receipt by DCO
5	Upon receipt of 'final state' of goods from supply chain, the data management service performs end-to-end corroboration of data and goods movement

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Assessment: Systems Integration Requirements

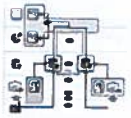
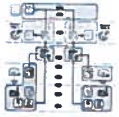
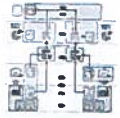
Feasibility Consideration: Different levels of automation across EU distributors & wholesalers

Large Operators with Automated Systems

- Interface specification to submit tobacco traceability events
- Suitable for large operators processes and systems
- Choice of integration with own Warehouse Management System (WMS) and/or Enterprise Resource Planning (ERP) applications
- Consideration of industry developed standards (GS1 EPCIS)
- Data submitted directly to the relevant data storage facility

Small & Medium Operators (Basic Systems)

- Standalone application & hand held readers
- Suitable for operators with low system integration
- Facility to record associated commercial event information (order, invoice and payment records)
- May result in parallel processing effort (for tobacco products)
- Standalone application submits data to data storage facility

	Option 1	Option 2	Option 3	Option 4
				
Differences across 4 options	Standalone solution provided by Tobacco Manufacturers	Standalone solution provided by Solution Provider(s)	Combination of Option 1 and 2	Standalone solution provided by Solution Provider(s)

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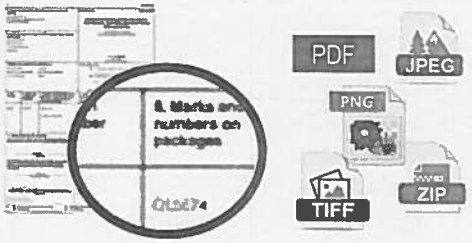
Related Commercial Documents

Linking of supporting commercial documents to traceability events (invoice, order number, payment records)

	By link to document reference #	Submitted as supporting document	Submitted as electronic d... "Dematerialised Data"
ILLUSTRATION	<OrderNumber> 002980040 <InvoiceNumber> A794890001		BIG*040713*1001*040625*PB9320~ Document Header REF*AN*547794~ PER*BD*JOHN JONES*TE*5552225555~ N1*BT*ACME DISTRIBUTING COMPANY~ N3*601 FIRST STREET~ N4*CROSSROADS*MI*48106~ FOB*PB~ Document Line Items CTP*RS*FCP*12.5~ PID*F*08***ITEM DESCRIPTION 1/10 LB~ SAC*A*B280***20.00***2.00****02~
Documents available on Request	✓	✓	✓
Immediately available to EU & MS Officials	-	✓	✓
Prevent document changes after submission	-	✓	✓
Format suitable for automated analysis (e.g. risk engine processing)	-	-	✓
Implementation Complexity for Stakeholders			
Extended support for automation of Law Enforcement & other Traceability objectives			

Low Medium High

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Overview of a Traceability Solution

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- Security feature
- Aggregation

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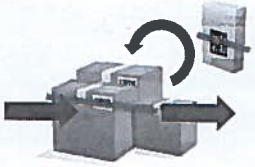

Data Storage Providers

- Independent storage of traceability data

Member State Users

- Monitoring, control and enforcement activities.
- Queries, analysis or integration with Member State systems

European Union Users

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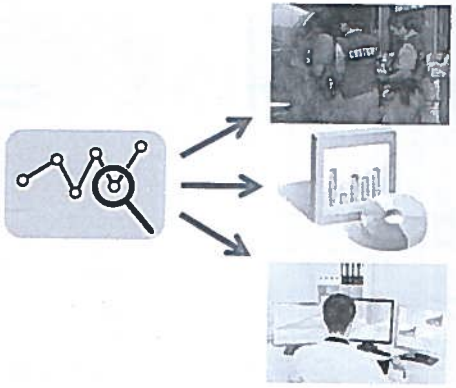

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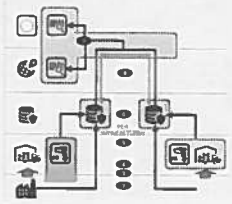
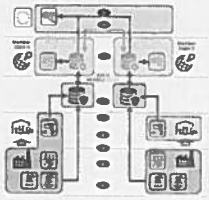
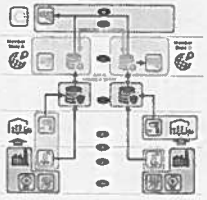
Assessment: Data Management

	Option 1	Option 2	Option 3	Option 4
				
Proposed By:	Manufacturer	EU Commission	Member States	Member States
No of Operators:	Up to ±230 (Manufacturers)	1	Up to 28	Up to 28
Location of Data:	In EU Territory	In EU Territory	In Member State	In Member State
Traceability Data Oversight	Low	High	Medium	Medium
Responsiveness	Low	High	Low	Low
Complexity (& Data Quality Risk)	High	Low	High	High

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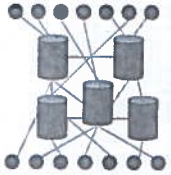
Assessment:
Data Management – One or Many Providers



Number of Sites	One (Consolidated - Option 2)	Many (Fragmented Option 1, 3 & 4)
Advantages	▪ Low risk of data compatibility issues ▪ Simpler to get consolidated view of all events ▪ Less complexity to determine location for data updates ▪ Centralised control and management of data sources ▪ Consolidated disaster recovery and failover efforts ▪ Economies of scale cost advantage ▪ Single Point of access for integration with other systems (E.g. EMCS)	▪ Faster response times for local queries ▪ Local network link failure impact constrained to local sites only ▪ Spreads the economic opportunity to potentially 28 operators
Disadvantages	▪ Increased response time latency at remote sites for transaction type queries ▪ Lower Fault tolerance ▪ Potential question over scalability	▪ Slow response times for multi-site queries ▪ Duplicated site overhead costs ▪ Redundancy of disaster recovering planning and testing efforts ▪ Increased change management (changes and testing efforts) ▪ No cost economies of scale advantage ▪ Administrative overhead for EU Commission / Member States / Manufacturers requiring multiple selection, bid and contract management activities

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Assessment: Summary for Data Management

Anticipated that traceability Data Size is manageable

- Operational data size of approximately 2 TiB per year is not considered an impediment for solution operation, or for consolidation to a single EU data repository
- Seven years of data (static market conditions) would be ~16 TiB
- Further optimization techniques possible:
  - Data compression techniques could reduce further
  - Data storage is tiered (e.g. most current 2 years online, 3-5 years on slower disk, 6+ archived)

Pack level Tracking is Feasible

- From data storage perspective, operating solution at pack level, across the EU, is technically feasible

Consolidating to a single data storage facility

- Implementation for all solution users (Manufacturers, Distribution Chain Operators and EU Member States) would be simplified with the use of a single repository
- Therefore, given the size of the data sets, a single point on-line data storage provider is economically sensible, supports data integrity and is a practical solution.

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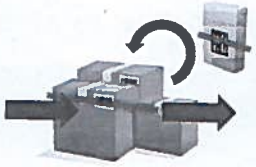

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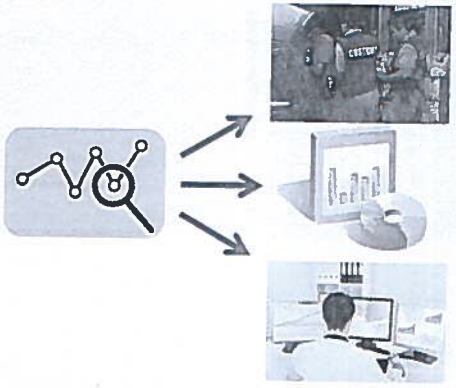

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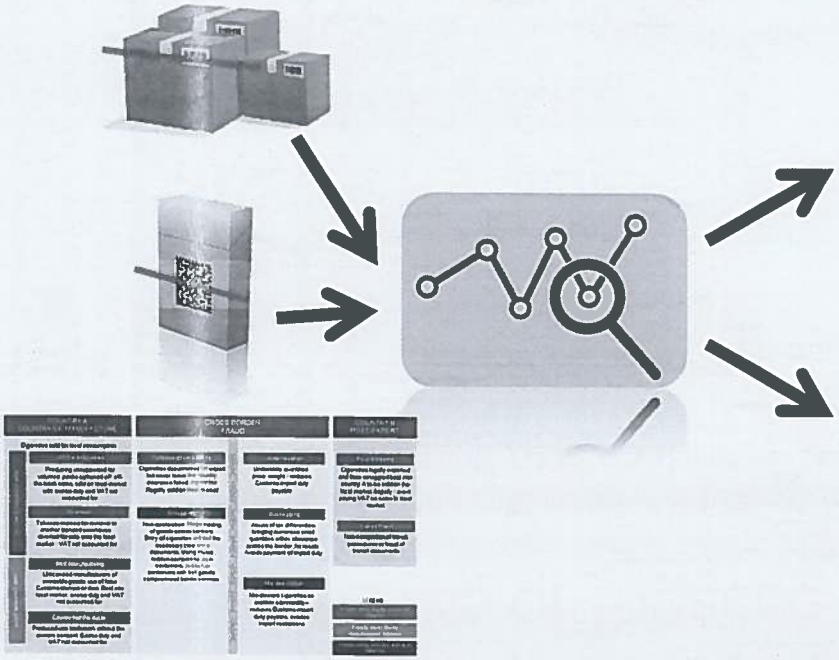
Assessment: EU & MS Users
Potential Benefits of Tobacco Traceability Data

While the primary purpose of the TPD in terms of tobacco traceability is reduction of non-compliant products entering the internal market – tobacco traceability data could also aid tax revenue management efforts in the tobacco sector.



Topology of Illicit Trade

Linkage with Excise Authorities

- Automated generation of supporting data for monthly Excise revenue declarations
- Linkage with Excise Movement Control System connects documentary controls to physical goods and provides data to support eAD and acquittal process

Linkages with Member State Authorities

- Control of Imported products: Provides Customs authorities at the border with ability to immediately determine status / legitimacy of tobacco products
- Control of Exported products: provides linkage to record of unique identifiers of actual tobacco products exported

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Assessment: EU & MS Users
Potential Benefits of Tobacco Traceability Data

While the primary purpose of the TPD in terms of tobacco traceability is reduction of non-compliant products entering the internal market – tobacco traceability data could also aid tax revenue management efforts in the tobacco sector.

Tactical Support for Market Surveillance Activities

- Full history of field inspection coverage (opportunity to show on geo maps)
- Identify non-compliance "hotspots" and limited coverage
- Oversight of market surveillance teams location and adherence to sampling methods.
- Measure target public health campaigns

Support Tax Audit Functions in Tobacco Sector

- Generate an overview of flows of manufactured, imported, exported and distribution of tobacco products
- Access detailed information on particular shipments & deliveries
- Information source to correlate production information with duty & VAT payments

Revenue Analysis and Forecasting

- Provides production data for forecasts of Excise Duty, VAT, and potentially Corporate tax collections
- Economic information for detecting economic cycles, seasonality and trends

Risk & Investigation

- Structured automated reports for reporting Member State compliance checking / audit at manufacturers distributors and at point of sale;
- Use geospatial mapping technology to visualize Inspection coverage, and heatmaps to shows areas of identified non-compliance.

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Assessment:
EU & MS Users Field Inspection Support

	Simple Traceability Application	Field Support Application
Intended Users	Police Services, Border Agencyies (Customs)	Enforcement Officials in the domain of tobacco control (OLAF Tobacco control, Excise Officers, market surveillance)
User Frequency	Occasional verification	Related to primary job function
Application Type	Web Portal (smartphone / SMS service)	Mobile Application / dedicated device
Connectivity Support	Online only	Online and offline
Functionality	• Manual capture or Scan • Simple Traceability Queries (Item information, Current Status, Previous Event History)	• Scan or Capture • Decode unique identifier (Offline) • Bulk capture (Offline) • Traceability Queries • Validate Aggregation Hierarchy • Inspection case workflow (capture of inspection results and findings, evidence capture using camera,
Activity Recording	• User, Access history, Location (IP Address)	• User, Access history, Location (GPS & IP Address)

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Assessment: Potential Integration with EMCS

European Commission

EMCS
Excise Movement Control System

- ✓ Linking Tobacco Traceability solution with EMCS and Exports creates a link between the physical goods and the existing documentary controls
- ✓ Traceability provides actual movements and details on exceptions (short shipments, returns) that can support the EMCS
- ✓ Different approaches to establish this link – some potential options:
  - Manufacturer / Distributor provide traceability data as a "supporting document" to e-AD; or
  - Introduce requirement for e-AD Movement Number to be submitted as part of traceability movement
- ✓ Advantages and Disadvantages of such approaches
  - Roles and mandates of respective systems;
  - Integrity of data and enabling downstream reconciliation processes
  - Implementation Complexity

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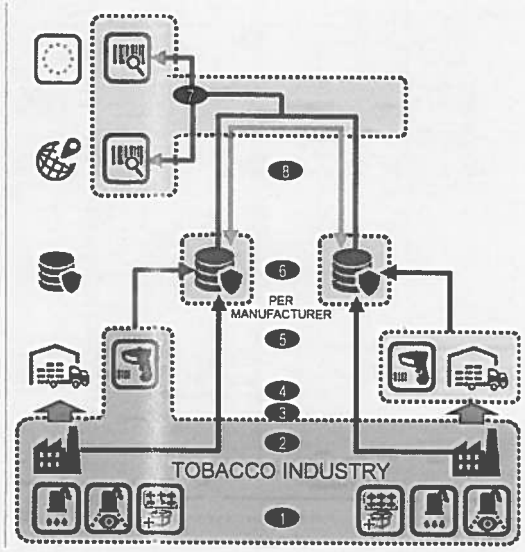
Summary of Advantages / Disadvantages

Note: Excludes costs (follows in next section)



Option 1

Advantages

- Low admin burden for EU & MS
- Competitive solution components costs
- Flexibility for manufacturers

Disadvantages

- Manuf. as only data source – therefore additional supervision required by MS
- Industry required to self-mediate with imbalance in org. sizes
- Risk as to reliable guarantee for independent control and management of pack codes
- Is shared industry software and systems free from vulnerabilities that may compromise integrity?

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Summary of Advantages / Disadvantages

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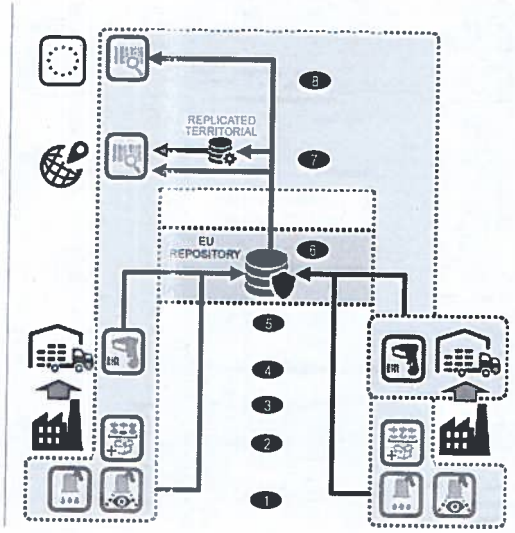

Option 2

Advantages

- Segregation reduces fraud risk
- Scale advantages
- Single location: -Simplified admin, supports complex analysis & improves oversight
- Interoperability creates competitive bid environment

Disadvantages

- Prescribed components reduce flexibility for manufacturers
- Additional mitigation required to not cause production down-time by 3rd party.

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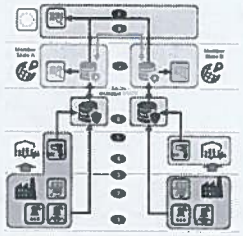
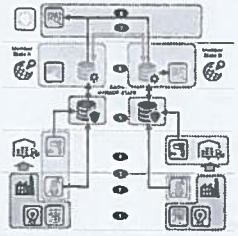
Summary of Advantages / Disadvantages

Note: Excludes costs (follows in next section)

	Option 3	Option 4
		
Advantages	▪ Autonomy and choice for MS ▪ Increased opportunity for smaller solution providers ▪ Member States flexibility in level of independence & control	▪ Retains independent oversight ▪ Reduced equip. requirements. ▪ Lower risk of prod. downtime. ▪ Control of SF stock ▪ Flexibility for manufacturers how to apply SF
Disadvantages	▪ Fragmentation increases complexity and cost ▪ Hinders coherent tobacco control strategy ▪ Depending on blend - option 1 and Option 2 disadvantages	▪ SF location potentially creates aggregation complexity ▪ Traceability queries require online connectivity ▪ Additional solution need for marking export products

Solution by Member State

- Higher implementation and change management effort
- Integration of Member State level data sources required for EU-level oversight and tools for EU Agencies.
- Potential system performance disadvantages.

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SECURITY FEATURE SUMMARY

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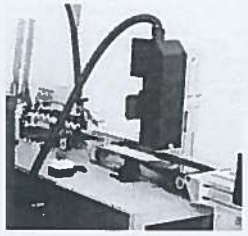
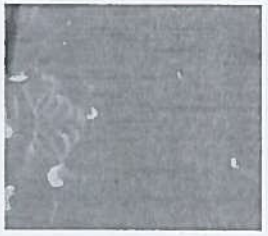
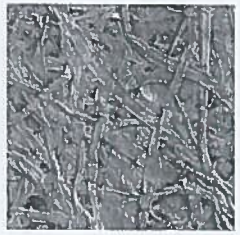
Security Feature: Method of Application

INCREASING CONTROL OF SECURITY FEATURE PRODUCTION

	INCORPORATE INTO COMMERCIAL PACKAGING	SPECIFIC PACKAGING ELEMENT	PRINT DIRECTLY ON FINISHED TOBACCO PRODUCT	PROVIDE AS A FINISHED LABEL OR STAMP	SECURITY FEATURE COMBINED WITH FINGERPRINTING
ADVANTAGES	• Low cost • Can be applied to multiple areas of packaging	• Single component to be controlled • Provides some indication of volume verification	• Cannot be removed or reapplied • Provides est. volume control • Suitable for highly automated manufacturing lines	• Offers overt,covert & forensic • Compatible with existing equipment • Established control mech. • Range of manufacturing (speed, volume and import) • Strong volume control element	• Strong covert authentication element • Unable to reuse • Used on pack or labels • Independent storage of the acquired "fingerprint" provides volume control element.
DISADVANTAGES	• Lower control • Limitation of security elements available commercially • Limited security, certification and rigor • Greater resulting variation • Intrusive on packaging design	• Additional complexity to ensure not removable	• Limited designs and flexibility • Constraints on packaging • Not suitable for low volume or non-automated production • Additional equipment on-line	• Typically standard sizes for application equipment • Requires stock & order management • Requires label applicators on production lines	• Higher cost (equipment on each line) • Limited available solution providers • Some impact on the packaging design process and enrolment of each brand / product packaging

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Security Feature: Summary Advantages & Disadvantages

Note: Excludes costs (follows in next section)

	OPTION 1 Similar to Tax Stamp	OPTION 2 Reduced Covert (semi-covert)	OPTION 3 Addition of Material "Fingerprint"	OPTION 4 Addition of Unique Identifier
ADVANTAGES	• Provides a competent mix of security feature elements with similar security value and cost as current tax stamps / labels. • Multiple security element layers (overt, covert and forensic) increase the difficulty for security feature to be counterfeited. • Supply & application is compatible with established processes and equipment currently used for tax stamps.		• Provides a control check of how many items have been enrolled • There is no trace of the area fingerprinted, making analysis and reproduction near impossible.	• The application of a unique identifier to each security feature enables the security feature to be controlled and tracked from the point of secure production
DISADVANTAGES	• Provides only basic method for stock control (no serial numbers)	• Provides only basic method for stock control (no serial numbers) • No semi-covert feature – therefore distributors / officials looking for more than overt feature authentication will require a device with online connectivity	• Some intrusion on manufacturing lines for installation of the enrolment devices. • Cost of capital equipment required on each production line. • Low number of available solution providers able to implement this solution.)	• Expected higher implementation cost (equipment on each line) • Limited available solution providers • Some impact on the packaging design process and enrolment of each brand / product packaging

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Agenda

1 Background & Context

- Project Status
- Deliverables & Tasks
- Constraints & Challenges
- Key Stakeholders
- Baseline for Analyses (Problem Statement)
- Relevant Benchmarks & Trends

2 Key Concepts & Methodology

- Traceability: Key concepts
- Security Features & Authentication: Key Concepts
- Project Methodology
- Stakeholder Engagements

3 Four Options Defined

- Overview of a Traceability Solution
- Description of the Four Traceability Solution Options
- Description of the Four Security Feature Options

4 Analyses and Outcomes

- Implications and Requirements
- Feasibility Concerns
- Additional Solution Considerations
- **Cost Benefit Analyses**
- Conclusions and Recommendations

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Benefit Analysis I – based on public data

Rational considered

Illicit trade as % of total market 8,25%

Illicit Trade break down	Contra-band	Counter-feit	Illicit whites
	30%	50%	20%
Estimated impact on illicit trade reduction	⇩ 30%	⇩ 10%	⇩ 10%
Impact quantification over total market (in %)	0,742%	0,413%	0,165%
	1,32%		

	Estimated impacts
Estimated impact on illicit trade reduction (in %)	-
Impact quantification on total market consumption (in %)	1,32%
Impact quantification on total market consumption (in M packs)	369
40% smokers quit or reduce smoking	
Consumption reduction (in M packs)	148
Number of people quitting smoking (in M people)	0,6
Increase in society productivity (in M euros)	44
Reduction on public health expenses (in M euros) (A)	134
60% smokers will 'go legal'	
New legal sales (in M packs)	221
New tax revenues from VAT (in M euros) (B)	169
New tax revenues other than VAT (in M euros) (C)	567
Total Public benefits (in M euros) (A + B + C)	870

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Benefit Analysis II – based on other information available

Rational considered

- Recognizing that publicly available studies are two or three years old…
- … and that changes could have in the meantime occurred on the size of the illicit market as well as on the breakdown of illicit trade
- Contracting team has decided to look for alternative sources, eg Euromonitor, that assess the illicit segment in the EU as **10% of the total market**
- Using this figure as a reference, we have then prepared a sensitivity analysis, where 3 scenarios were analysed:
  - a 10% impact on illicit trade would mean a "low" outcome
  - 20% would correspond to a "medium" outcome
  - and 30% to a "high" one

	Low impact	Medium impact	High impact
Estimated impact on illicit trade reduction (in %)	*10%*	*20%*	*30%*
Impact quantification on total market consumption (in %)	*1,00%*	*2,00%*	*3,00%*
Impact quantification on total market consumption (in M packs)	*279*	*558*	*838*
40% smokers quit or reduce smoking			
Consumption reduction (in M packs)	*112*	*223*	*335*
Number of people quitting smoking (in M people)	*0,5*	*1,0*	*1,4*
Increase in society productivity (in M euros)	*33*	*66*	*99*
Reduction on public health expenses (in M euros) (A)	*101*	*202*	*304*
60% smokers will 'go legal'			
New legal sales (in M packs)	*168*	*335*	*503*
New tax revenues from VAT (in M euros) (B)	*128*	*256*	*384*
New tax revenues other than VAT (in M euros) (C)	*429*	*857*	*1 287*
Total Public benefits (in M euros) (A + B + C)	*658*	*1 317*	*1 975*

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Sum up Benefit Analysis + Sources of information

Sum up benefit analysis

Benefit Analysis I – based on public data

Impact quantification on total market consumption (in %)

	Total Public benefits (in M euros)
1,32%	***870***

Benefit Analysis II – based on other information available

Impact quantification on total market consumption (in %)

		Total Public benefits (in M euros)
Low impact	***1,00%***	***658***
Medium impact	***2,00%***	***1 317***
High impact	***3,00%***	***1 975***

Sources of information considered (not exhaustive)

- European Commission – Impact Assessment for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products
- Economic Analysis of the EU market of tobacco, nicotine and related products – Matrix Insight, 2013
- WHO Tob Taxy Capacity Building Workshop – Dublin, Ireland; February 2012; World Bank Economics of Tobacco Toolkit – Economic Analysis of Tobacco Demand
- Project Sun - A study of the illicit cigarette market in the European Union – KPMG, 2013
- Eurostat: people by age group and share of total population
- http://ec.europa.eu/health/tobacco/policy/index_en.htm
- http://ec.europa.eu/taxation_customs/index_en.htm#
- http://en.wikipedia.org/wiki/List_of_countries_by_tax_rates
- WAP from EC Excise Duty tables Part III – Manufactured Tobacco and manufacturer estimates for non-EU countries;

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Cost analysis rational

Cost nature considered for each stakeholder

Stakeholders considered on the cost analysis

Manu-facturers	❑ Investment costs (one-off): Pack printer and installation; Aggregation costs; Carton printing, with applicator; Case label printing; Pallet label printer; Server and software; Kit (PC + 2 scanners); Other installation local support not included above; IT System development ❑ Operating costs: Packaging and labelling; Server and software maintenance; Depreciation; Global traceability database: hosting & maintenance; additional HR costs; registration costs; IT System maintenance
Whole-salers	❑ Investment costs (one-off): server & software; Kit (PC + 2 scanners) ❑ Operating costs: software maintenance costs, anual depreciation, registration costs, additional HR costs
Vending Machine Service Vans	❑ Investment costs (one-off): server & software; Kit (PC + 2 scanners) ❑ Operating costs: software maintenance costs, anual depreciation, registration costs, additional HR costs
Mobile Sales Force Units	❑ Investment costs (one-off): server & software; Kit (PC + 2 scanners) ❑ Operating costs: software maintenance costs, anual depreciation, registration costs, additional HR costs
Member States	❑ IT system development costs ❑ MS incremental labour costs

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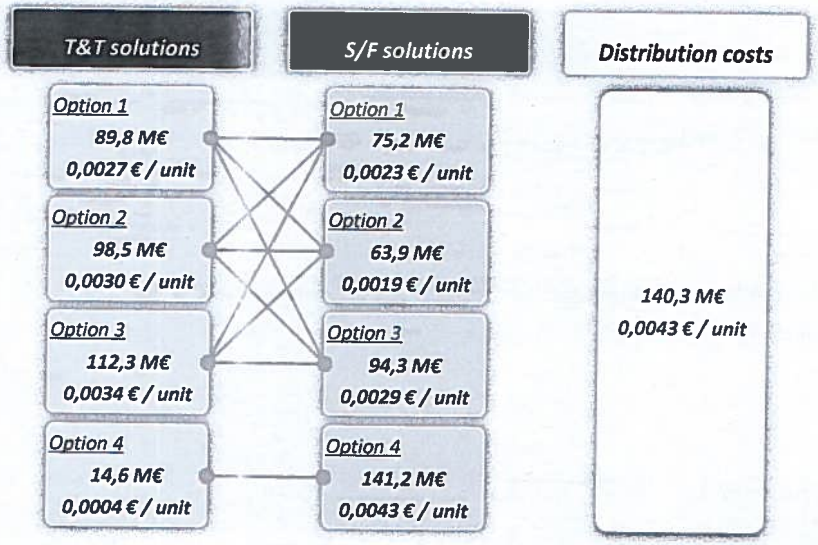
Cost analysis – value chain main stakeholders



	S/F Option 1	S/F Option 2	S/F Option 3	S/F Option 4
T&T option 1	305,3 M€ 0,0093 € / unit	294,0 M€ 0,0089 € / unit	324,4 M€ 0,0099 € / unit	-
T&T option 2	314,0 M€ 0,0096 € / unit	302,7 M€ 0,0092 € / unit	333,1 M€ 0,0102 € / unit	-
T&T option 3	327,8 M€ 0,0100 € / unit	316,5 M€ 0,0096 € / unit	346,9 M€ 0,0106 € / unit	-
T&T option 4	-	-	-	296,1 M€ 0,0090 € / unit

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Cost analysis – value chain main stakeholders: zoom in

T&T Cost analysis for MANUFACTURERS

T&T cigarette costs

	Option 1	Option 2	Option 3	Option 4
Development Costs (CAPEX)	122,1 M€	122,1 M€	122,1 M€	77,0 M€
Annual depreciation	20,3 M€	20,3 M€	20,3 M€	12,8 M€
OPEX	66,2 M€	66,2 M€	66,2 M€	0,6 M€
Additional costs	-	8,7 M€	22,5 M€	-
Annualized total costs	86,5 M€	95,2 M€	109,0 M€	13,4 M€
Average € / unit (1)	0,0026	0,0029	0,0033	0,0004

T&T cigar costs

	Option 1	Option 2	Option 3	Option 4
Development Costs (CAPEX)	5,5 M€	5,5 M€	5,5 M€	5,5 M€
Annual depreciation	0,9 M€	0,9 M€	0,9 M€	0,9 M€
OPEX	2,4 M€	2,4 M€	2,4 M€	0,3 M€
Annualized total costs	3,3 M€	3,3 M€	3,3 M€	1,2 M€
Average € / unit (1)	0,0001	0,0001	0,0001	0,0000

S/F Cost analysis for MANUFACTURERS

	Option 1	Option 2	Option 3	Option 4
Development Costs (CAPEX)	-	-	33,5 M€	-
Annual depreciation	-	-	5,6 M€	-
OPEX	75,2 M€	63,9 M€	88,7 M€	141,2 M€
Annualized total costs	75,2 M€	63,9 M€	94,3 M€	141,2 M€
Average € / unit (1)	0,0023	0,0019	0,0029	0,0043

Cost analysis for WHOLESALERS

	Wholes.	VMSV	MSFU	TOTAL
Development Costs (CAPEX)	137,7 M€	21,4 M€	40,4 M€	199,5 M€
Annual depreciation	23,0 M€	3,6 M€	6,7 M€	33,2 M€
Maintenance Costs (OPEX)	51,9 M€	21,0 M€	34,2 M€	107,1 M€
Annualized total costs	74,9 M€	24,6 M€	40,9 M€	140,3 M€
Average € / unit (1)	0,0023	0,0008	0,0012	0,0043

Wholesalers; Vending Machine Service Vans; Mobile Sales Force Units

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Cost analysis – Member States

IT system development costs (in M€)

T&T options

	Option 1	Option 2	Option 3	Option 4
Development Costs (CAPEX)	1,5 M€	0,8 M€	2,0 M€	2,0 M€
Annual depreciation	0,3 M€	0,2 M€	0,3 M€	0,3 M€
Maintenance Costs (OPEX)	0,2 M€	0,1 M€	0,3 M€	0,3 M€
Annualized total costs	0,5 M€	0,3 M€	0,6 M€	0,6 M€

Considering an average daily charge rate of 700 €

	Option 1	Option 2	Option 3	Option 4
Development Costs (CAPEX)	2,5 M€	1,5 M€	3,5 M€	3,5 M€
Annual depreciation	0,4 M€	0,3 M€	0,6 M€	0,6 M€
Maintenance Costs (OPEX)	0,4 M€	0,2 M€	0,5 M€	0,5 M€
Annualized total costs	0,8 M€	0,5 M€	1,1 M€	1,1 M€

Considering an average daily charge rate of 1.200 €

MS incremental labour costs (in k€)

T&T options

	HC	Option 1	Option 2	Option 3	Option 4
MS "A"	28	75,2 k€	18,8 k€	37,6 k€	18,8 k€
MS "B"	65	162,8 k€	40,7 k€	81,4 k€	40,7 k€
MS "C"	155	492,5 k€	123,1 k€	246,2 k€	123,1 k€
MS "D"	33	314,3 k€	78,5 k€	157,2 k€	78,6 k€

MS incremental labour costs for inspection and audit roles

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Cost analysis – sources of information

Sources of information considered on the cost analysis (not exhaustive)

- Impact Assessment for a directive of the European Parliament and of the Council on the approximation of the law, regulations, and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products'
- Industry – solution provider's survey
- Matrix insight - Economic analysis of the EU market of tobacco, nicotine and related products, September 2013
- The European Tobacco Sector: an analysis of an socio-economic footprint; Nomisma, June 2012
- WHO
- Euromonitor Database
- Eurostat Database
- OLAF
- DCTA
- MSN, Azure
- Others:
  - Industry surveys
  - Surveys to MS / Excise agencies

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Summary: Conclusions

Overall Feasibility Assessment

- Required technology components exist today
- Number of solution providers with required competence
- Existing industry standards provide basis for interoperability & information exchange
- Data sizes manageable (centralised repository possible)
- Several choices of security features for overt, covert and forensic elements

Specific Feasibility Concerns

- Data elements that can be included as part of unique identifier
- Submission of related commercial documents (invoice, order, payment records)
- No one-size fits all – differences between scale of FMC, OTP and variety of Distribution Chain Economic operators
- Consideration of size and placement constraints

Additional Considerations

- Benefits from linkages with EMCS, Import and Export systems
- Additional Member State supervision controls and use of Traceability Data
- Security Feature important complimentary control of the Traceability Solution

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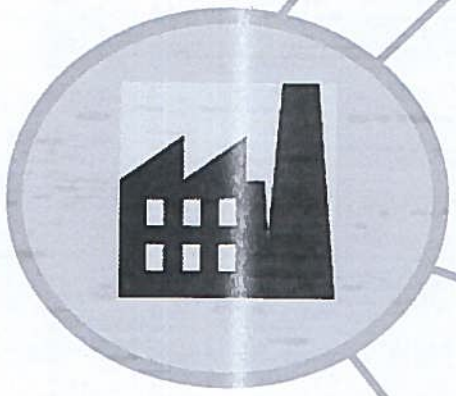
Traceability during Tobacco Manufacturing

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.



Options

- Security Elements in the Security Feature
- Serialisation by manufacturers or 3rd party
- Application directly onto pack or by label

Considerations

- Data elements forming part of the unique identifier or accessible by link
- Method to ensure unique identifiers are unique across manufacturers, solution providers, Member States (and potentially globally)
- Large automated vs low volume crafted tobacco products

Decisions

- Functions performed by manufacturers vs independent parties
- Mechanisms / measures to monitor integrity of the traceability solution

Costs

- Option 1: 89,8 M€ (annualized total costs) – 0,0027 € / pack
- Option 2: 98,5 M€ (annualized total costs) – 0,0030 € / pack
- Option 3: 112,3 M€ (annualized total costs) – 0,0034 € / pack
- Option 4: 14,6 M€ (annualized total costs) – 0,0004 € / pack

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Traceability in the Tobacco Distribution Chain

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.

Options

- Integration with economic operators existing ERP / WMS systems; OR
- Use of standalone traceability solution for tobacco
- Link / submission of commercial documents

Considerations

- Link / align with existing systems and practices (e.g. inventory / warehouse management systems)
- Link with EMCS, Import & Export
- Supply chain self-regulating compliance

Decisions

- Direct vs. implied traceability
- Product coverage
- SME exceptions
- Who provides the standalone solution

Costs

- Wholesalers: 74,9 M€ (annualized total costs) – 0,0023 € / pack
- VMSV: 24,6 M€ (annualized total costs) – 0,0008 € / pack
- MSFU: 40,9 M€ (annualized total costs) – 0,0012 € / pack

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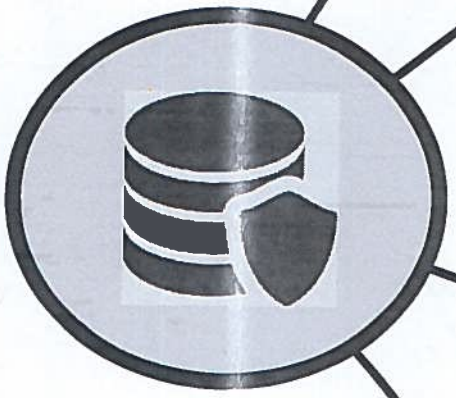
Traceability Data Management

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.



Options

- Single or 28 Sites
- Discovery Service (for multiple sites)
- Source of alerts and notifications

Considerations

- Multiple Storage Locations will multiple costs x 28
- Implications on performance, complexity & quality
- National vs EU Community & Confidentiality

Decisions

- Single or Multiple
- Define "who" can be a 3rd party

Costs

- Server hosting - Option 1: 17,4 K€ (annualized cost)
  Option 2 – 69.4 k€ (annualized cost)
  Options 3 / 4 - 34.7 k€ (annualized cost)
- Data hosting - 6.2 K€ (annual cost)

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Traceability System Users

Each tobacco item is marked with a unique identifier and security feature. Aggregation, movement and dispatch events are recorded.

Options

- Developed at EU Level (and shared), or by individual Member States
- Use of software provided by solution provider
- Degree of data replication to support analysis

Considerations

- User(s) Access and to what level
- Method for generating a consolidated view (across data repositories)
- Management of cases and workflow

Decisions

- Who will manage the access (a body or entities?)
- Synergies and shared components vs. Member State autonomy

Costs

- Option 1: between 0,469 M€ and 0,804 M€ (annualized cost)
- Option 2: between 0,269 M€ and 0,462 M€ (annualized cost)
- Options 3 / 4: between 0,648 M€ and 1.112 M€ (annualized cost)

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Feasibility Study Key Findings

1. **Implementation of traceability is feasible**
   - Technology exists
   - Diverse market of suppliers
   - Emerging technologies & solutions are proliferating
   - Traceability is a growing trend globally
   - The needs of multiple stakeholders can be met

2. **There is no one size fits all solution (or provider)**
   - There are a multitude of ways this can be done (with differing results, impact and consequence)

3. **Some key decisions need to be further explored and considered and this report provides a key input into that process.**

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Summary: Recommendations & Going Forward

- Planned and co-ordinated change effort for impact on manufacturers and distribution chain operators. Ideally would include technical participation by EU Member States and EU Commission participants in a working stakeholder body
- Use of industry standards for marking (symbology), recording and data exchange of traceability events is key for a interoperable solution compatible across operators and member states
- Distribution chain readiness – offer choice of compliance by conforming own systems to standards, or use of standalone application
- For SME and OTP: consider blend of options, with integrated security feature and traceability suitable for the smaller operators
- There is a cost and operational advantage for EU Member States with existing tax stamp programmes to, as far as possible, combine these with the security feature requirements
- MS should working group to develop requirements for traceability application suite
  - Requirements for interfaces with existing systems
  - Support for enforcement programmes

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