Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products

Final Report

Annex I – Evaluation of Policy Options

Service Contract N° 2015 71 05

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E-mail: *CHAFEA-HP-TENDER@ec.europa.eu*

SANTE-B2-Tobacco-Control@ec.europa.eu

European Commission
B-1049 Brussels

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0. INTRODUCTION

The following document serves as the Final Report to the European Commission´s Consumers, Health, Food and Agriculture Executive Agency (Chafea) in response to the request for service Chafea/2015/health/40 for the implementation of Framework Contract FWC DIGIT/R2/PO/2013/004 ABC III Lot 2, concerning the **implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products**.

The present document is the Annex I of the study carried out, and is complemented by:

- Main Report
- Annex II – Technical Specifications of the Tracking and Tracing System and the Security Features
- Annex III – Model Contract

All these documents are made public, and can be requested under the following publication numbers:

Volume	Catalogue number	ISBN	DOI
Main Report	EB-02-17-895-EN-N	978-92-9200-770-6	10.2818/453932
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Annex III – Model Contract	EB-02-17-898-EN-N	978-92-9200-876-5	10.2818/751591

1. TECHNICAL EVALUATION OF POLICY OPTIONS

1.1. Definition of the policy options

The policy options were mainly drawn from the results of the Inception Impact Assessment. In this document, a set of options was defined per key decision point (i.e. who, where, how and when, for tracking and tracing; and how, for security features). Everis analysed these options, and based on its expertise and specific knowledge acquired during the course of Work Package 1, proposed refining the policy options, which are now as presented below.

Tracking and tracing				Security features
Who?	**Where?**	**How?**	**When?**	**How?**
(A) Governance model	**(B) Data storage model**	**(C) Allowed data carriers**	**(D) Allowed delays in reporting events**	**(S) Method of adding a security feature**
(A1) Industry operated solution	**(B1)** Centralised model	**(C1)** System with a single data carrier for all identification levels	**(D1)** Near real-time reports	**(S1)** Affixing
(A2) Third party operated solution	**(B2)** Decentralised model per manufacturer/ importer	**(C2)** System with a single data carrier per identification level and optional data carriers for aggregation packaging levels	**(D2)** One-day delay reports	**(S2)** Printing or integrating through a different method
(A3) Mixed solution (industry and third party)	**(B3)** Decentralised model per Member State	**(C3)** System with a limited variety of data carriers for all identification levels	**(D3)** One-week delay reports	**(S3)** Mixed solution
-	**(B4)** Combined model: centralised for surveillance and decentralised for recording per manufacturer/ importer	**(C4)** System with limited variety of data carriers for all identification levels and optional data carriers for aggregation packaging levels	-	-
-	-	**(C5)** Free system allowing any existing approved data carrier	-	-

Table 1: Policy options based on the Inception Impact Assessment

1.1.1. Governance model

The first policy approach in the definition of the system is the choice of its governance model. This defines and monitors the required level of system integrity by allocating various responsibilities and functions to the operators involved in the supply chain, starting with the manufacturers and providers of necessary services. This allocation must first guarantee the fulfilment of the objectives of the system. Secondly, it must be done in a cost-efficient manner, without undermining the objectives of the system, and while meeting the defined primary and secondary requirements.

Three levels of operation are considered in the governance model: the production of unit packets of tobacco products, the aggregation packaging levels of tobacco products and the potential re-aggregations that may occur along the supply chain. The first two operations fall under the responsibility of the manufacturers and importers of tobacco products, while the last one is under the responsibility of those distributors and wholesalers that could disaggregate and later re-aggregate the tobacco products (in the cost analysis performed in Chapter 2, those distributors and wholesalers are labelled and quantified as 'big distributors').

The different areas of the governance model are represented in the diagram below:

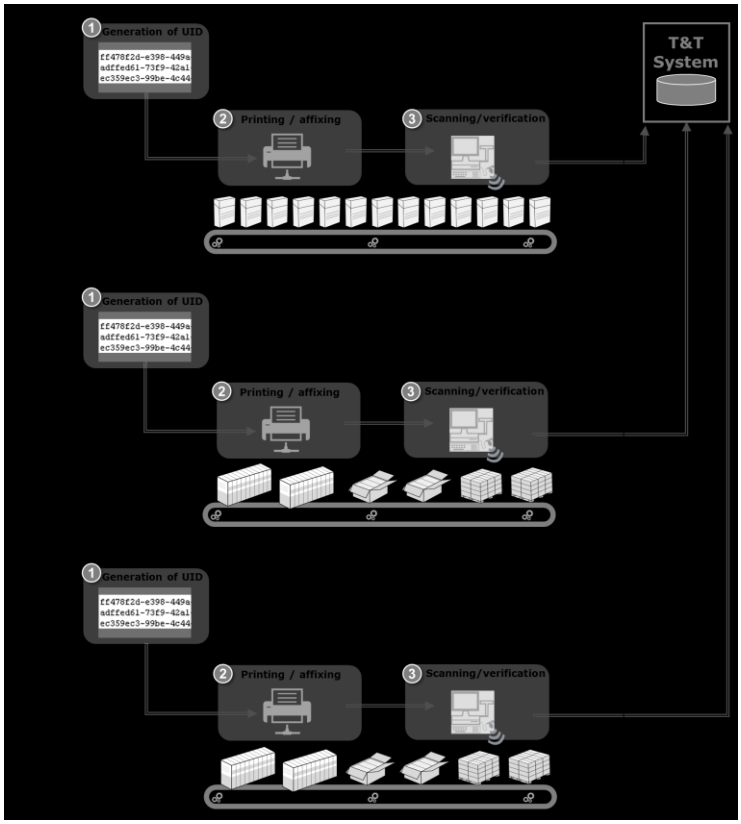


Figure 1: General overview of actions to be allocated in the governance model

Regarding the allocation of responsibilities and functions, the TPD defines the individual stakeholders that are responsible for several processes. However, there are additional responsibilities that may be considered integral to the functioning of the system. These include:

- The generation of the unique identifier for each unit packet of tobacco products and the different aggregation packaging (and re-aggregation) levels. For the allocation, control, maintenance and interoperability of unique identifiers, international open standards shall be prioritised. According to the requirements of the TPD, the unique identifier shall allow several pieces of information to be determined. Some of these elements need to be included in the unique identifier by the manufacturers and importers at the moment of the production, which represents a technical challenge from a governance perspective.

- The printing or affixing of the unique identifier on the tobacco unit packets and the different aggregation packaging (and re-aggregation) levels.
- The verification of the unique identifier.

The Inception Impact Assessment (European Commission - TPD Inception Impact Assessment, 2016) proposes three different options for the governance model:

Option A1: Industry operated solution

Option A2: Third party operated solution

Option A3: Mixed solution (industry and third party)

The proposed options cover the two extremes (a solution operated at all stages by the industry (manufacturers, distributors and wholesalers) and a solution operated at all stages by a third party). A third option is also included, which is a mixed approach where responsibilities and functions are allocated individually to the industry or a third party.

In the following sections, the three options (A1, A2, and A3) are explained in detail, keeping in mind the considerations above.

1.1.1.1. Industry operated solution

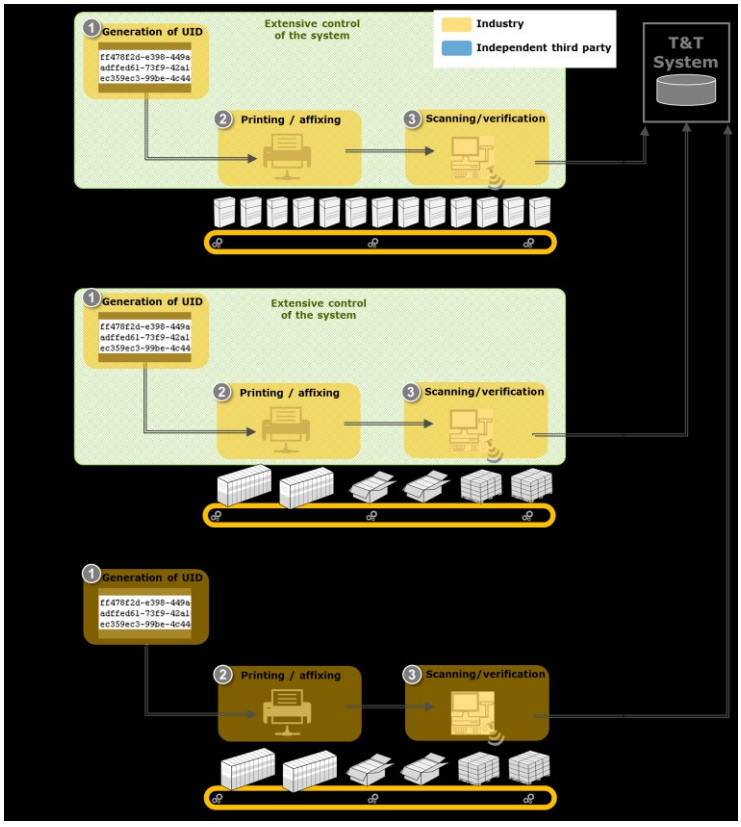


Figure 2: Allocation of the areas of responsibilities and functions in Option A1 – industry operated solution

In this option, the manufacturers and importers are responsible for (1) the processes related to generation of the unique identifiers for unit packets of tobacco and the aggregation packaging levels; (2) the printing or affixing of the unique identifiers for the

unit packets of tobacco and the aggregation packaging levels; and (3) the scanning/verification of the unique identifiers.

Big distributors[1] may re-aggregate cartons to mastercases and mastercases to pallets. Under this governance model, they are entitled to generate the codes and print/affix them into the re-aggregation levels. It is not foreseen that distribution chain operators other than big distributors will create re-aggregation levels. Economic operators other than big distributors (for example, distributors of other tobacco products) may also take the decision to install equipment to mark and scan the codes, and thus would be allowed to re-aggregate.

This option is likely to require fewer technical adaptations on behalf of the manufacturers and importers, as it may be possible for them to make use of existing systems and infrastructures[2]. However, in order to guarantee the independence and transparency of the system, further controls would be necessary. In particular:

- Active controls would need to be implemented by the competent authorities[3] during the processes of the generation of the unique identifiers and the printing or affixing, in order to ensure that all unit packets of tobacco products are marked and that the unique identifiers are indeed unique.
- Regardless of the active controls, passive control of the system is also required by means of regular and non-announced audits. These audits are needed across the different alternatives of the governance model.

The described option A1 shall not be confused with current track and trace solutions developed and implemented by the industry. The functioning and management of data of the current solutions developed are completely unknown for the competent authorities and do not comply with the binding legal requirements.

[1] We estimate that most of the re-aggregation processes (if not all) are done by the big distributors of the supply chain (2450 according to the figures available). Economic operators in the supply chain other than big distributors would be allowed to re-aggregate only if they install the needed equipment to mark and scan re-aggregated levels. This would be an individual decision of each economic operator in the supply chain: (a) not to re-aggregate (scanning each of the items individually, or (b) installing the needed equipment to mark and scan the re-aggregation levels and, then, re-aggregating.

[2] However, the reuse of existing systems and infrastructures is still uncertain. The current T&T solution developed and implemented by the industry does not meet the requirements of the TPD. Therefore, the implementation of this option A1 would also require some investments for the industry (only with the current equipment developed by the industry they will not be able to implement option 1).

[3] These additional extensive controls include the full time physical presence of enforcement officers on the manufacturers' (and importers') facilities and/or technical solutions that ensure the verification of the marking of all unit packets of tobacco products produced or imported.

1.1.1.2. Third party (under close supervision of the competent authorities) operated solution

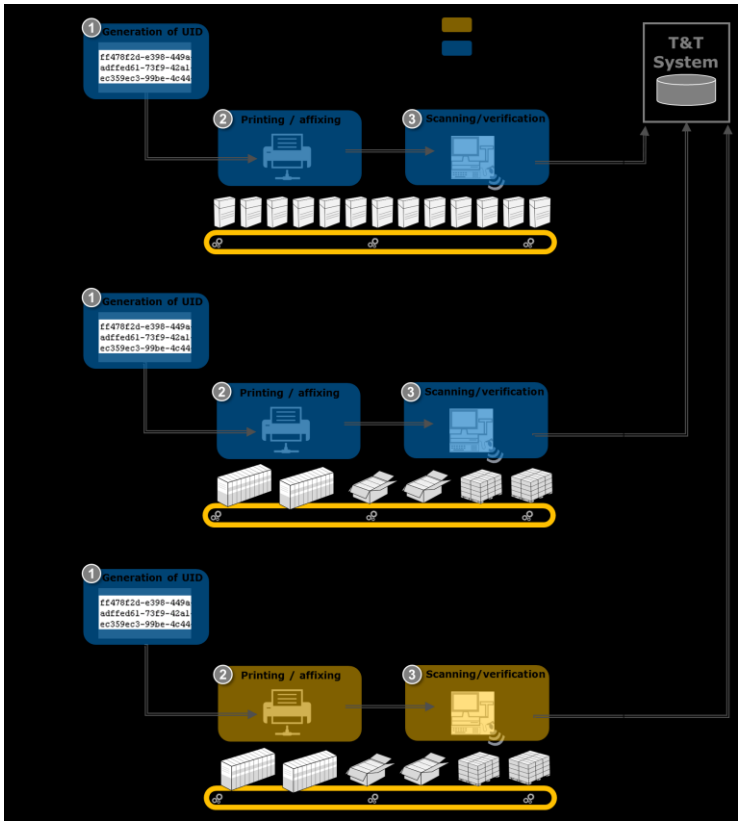


Figure 3: Allocation of the areas of responsibilities and functions in Option A2

In this option, independent third parties are responsible for the processes of generation of the unique identifiers, printing or affixing of the unique identifiers on the unit packets of tobacco (and aggregation packaging levels), and scanning/verification of the unique identifiers, always under the close control of the competent authorities.

The reporting of all movements of tobacco products to the data storage remains under the responsibility of the economic operators, as specified by Article 15.5 of the TPD.

The independent third parties will provide big distributors with the unique identifiers for the re-aggregation levels (mainly cartons to mastercases and mastercases to pallets). In option A2, it is foreseen that big distributors will print/affix the unique identifiers and scan and verify the codes themselves. Economic operators other than big distributors (for example, distributors of other tobacco products) may also take the decision to install equipment to mark and scan the codes, and thus would be allowed to re-aggregate.

Some considerations regarding independent third parties include:

- Member States must ensure that economic operators involved in the trade of tobacco products conclude contracts with independent third parties to perform the tasks described above.
- The Commission will be required to approve and appoint the independent third parties, only after verifying their independence and technical capabilities. Such an approval would need to be renewed periodically, as it is required that

independence and technical capabilities be maintained in the medium and long term. This assessment will ensure, for example, that the third party does not have a pre-existing financial or business relationship with the tobacco industry.

- The activities of the independent third parties must be under close and continuous control of the Competent Authorities.
- When determining the technical standards for the establishment and the operation of the Tracking and Tracing System, the Commission may include the obligation for economic operators to conclude contracts with an external auditor, in order to monitor the activities of the independent third parties[4]. This external auditor shall be proposed and paid by the tobacco manufacturers and approved by the Commission.
- It is foreseen that multiple independent third parties will be engaged in the process, as it is not feasible for a single entity to provide services to all the economic operators in Europe.
- In order to ensure interoperability among the different independent third parties, their activities must follow open standards.
- To avoid duplication and/or data collisions of unique identifiers in the Tracking and Tracing System, it is highly recommended to follow interoperable open standards (for example, ISO[5] standards) for assignment of "issuing agencies" for control of unique identifier prefixes. Within this system, additional controls are needed to mitigate the risk of a unique identifier being re-used.

The control performed is two-fold:

- Active and continuous control is ensured by the presence of independent third parties in the system. All solution components and cabinets installed and operated by the independent third parties at manufacturers' and distributors' premises must be fitted with adequate anti-tampering mechanisms to prevent access and manipulation by unauthorised parties. The independence of the third parties from the industry is monitored by:
    - The recurrent reassessment by the European Commission of the suitability of third parties;
    - The annual reports submitted by the external auditor on the activities of the third parties providing the service.
- Passive control is covered by regular and non-announced audits of the whole Tracking and Tracing System, performed by the competent authorities.

This option may provide a higher level of control and independence for controlling the System and fewer burdens for the competent authorities, when compared to an industry-operated solution. However, independent third parties must be granted permanent access to the facilities of the manufacturers, importers or distributors in order to install and operate their equipment (and maintenance) in the production lines of the manufacturers and importers, which may result in a significant impact on operational processes.

[4] Following the framework provided by the TPD for the data storage in art. 15.8.

[5] ISO 15459 (1-8) – Information technology – Unique Identifiers

A strong system of liabilities between the industry and the independent third parties must be developed, in order to prevent potential conflicts in case of interruptions in the production process, breach of contractual duties or negligent behaviour.

1.1.1.3. Mixed solution (industry and third party, under close supervision of the competent authorities)

In this option, the different processes and tasks for the operation of the Tracking and Tracing System are split between by the industry and independent third parties, resulting in a mixed solution.

The main benefit of this alternative is that it may enable certain existing infrastructures to be better utilised and avoid unnecessary duplications of procedures, whilst enabling authorities to exercise overall control of the system via the allocation of certain critical responsibilities to non-industry actors, including state agencies and independent third parties. This alternative allows full control of the system with minimum disruptions in the production process and may aid the implementation of protocols.

An optimal allocation of tasks would be one where processes that can contribute to the independence of the system (i.e. generation of the unique identifiers) are allocated to an independent third party (or performed by the competent authorities themselves). The processes that can make the system more operable or technically more feasible (printing or affixing the unique identifiers, scanning/verification) are then assigned to the industry.

The allocation of tasks must be done ensuring that the control of the system by the competent authorities is maintained at all times.

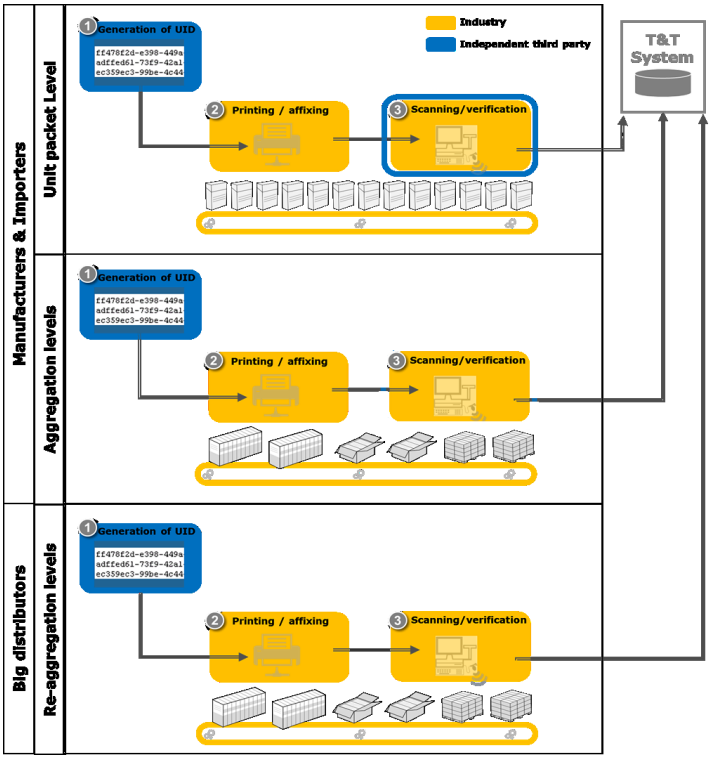


Figure 4: Proposition of optimal allocation of the areas of responsibilities and functions in Option A3

In the above configuration, the codes for the unique identifiers of tobacco products are generated by an independent third party (under the control and supervision of the

competent authorities) or the competent authorities themselves[6]. This way, the codes can only be produced via a central server controlled directly or indirectly (through an independent third party) by a competent authority. To request codes, manufacturers and importers must register with the central server and only the allocated codes will be authorised for use in production.

The industry may perform the scanning/verification of the codes, but a third party may be asked to install anti-tampering devices in order to introduce necessary checks over this process, which will provide the competent authorities with full control of the system.

In this option, the industry is in charge of the operational (hardware) processes of the system (marking all unit and aggregated packets of tobacco and reporting all movements to the data storage). The impact on the production lines of the industry is minimised while ensuring full control of the generation of the codes and the unit packets marked.

The same schema applies for the potential re-aggregation performed by the big distributors: they can request codes from the central server, marking and scanning by themselves the re-aggregations created. Economic operators other than big distributors (for example, distributors of other tobacco products) may also take the decision to install equipment to mark and scan the codes and thus, would be allowed to re-aggregate.

When the generation of the unique identifiers is assigned to an independent third party, the activities of this third party should be monitored by an external auditor.

The control in this option is ensured through:

- Active and continuous control performed by the generation of the codes by authorised parties only (independent third party or competent authorities). This generation is independent of the industry. Reconciliation between the codes generated, unit packets marked, and aggregation packaging levels is done at the data storage level.
- Permanent control is implemented for the scanning/verification of the codes by means of anti-tampering devices installed by an independent third party.
- Passive control is performed by the recurrent and non-announced audits performed by the competent authorities to the whole system and each specific manufacturer, distributor, retailer and logistics chain operator. The audits must be performed with higher frequency in Option A3, as there are more actions performed by the industry.

1.1.2. Data storage models

The second policy approach decision in the definition of the system is that of the data storage model.

The aim of the data storage is to store all relevant data reported by the economic operators, assure its integrity, and make it accessible to the competent authorities for surveillance purposes. To this end, the data storage model should firstly, guarantee the

[6] There could also be room for collaboration between the competent authorities (Member States or government agencies) and a third party for the generation of the unique identifiers. For example, 22 of the 28 Member States have a tax stamp system for cigarettes and, in most cases, it is a government agency working with a third party that is responsible for the tax stamp system.

fulfilment of the objectives of the system as required by the TPD, and secondly, be implemented in a cost-efficient manner, and while meeting the defined primary and secondary requirements.

This policy is referred to in the Inception Impact Assessment as the "location" of the data storage. However, the Interim Report II refers to it as data storage "model" because the concepts analysed for each option are broader than just "where" the data storage is physically located.

The Inception Impact Assessment proposed two different options for the data storage model: B1) Centralised data storage; and B2) Decentralised data storage. However, the decentralised option can be further extended, applying different criteria to distribute data across repositories (i.e. per manufacturer/importer or per Member State). Moreover, a combined model has been evaluated as well, which attempts to integrate benefits from both centralised and decentralised models.

Hence, this study assesses the following options for data storage models:

Option B1: Centralised model

Option B2: Decentralised model per manufacturer/ importer

Option B3: Decentralised model per Member State

Option B4: Combined model: centralised for surveillance and decentralised for recording (per manufacturer/ importer)

All of the proposed models are able to fulfil the following requirements of the TPD and the FCTC Protocol:

Legal reference	Requirements related to the data storage
TPD Art. 15(4)	The **trade information, required under TPD Art. 15(2)(i)(j) and (k), shall be electronically accessible** by means of a link to the unique identifier. *This information may be known at the time of manufacturing, and as such it is reported to the data storage once it has been confirmed by the parties involved.*
TPD Art. 15(5)	All **economic operators** involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, **shall record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit** of the unit packets from their possession. The recording of **aggregated packaging** such as cartons, mastercases or pallets, may help complying with the former.
TPD Art. 15(7)	All economic operators shall **transmit the recorded data** electronically **to a data storage facility**.
TPD Art. 15(8)(1)	The **manufacturers and importers of tobacco products shall conclude data storage contracts** with an independent third party.
TPD Art. 15(8)(1)	The data storage facility shall be physically located on the territory of the Union.
TPD Art. 15(8)(2)	The third party's activities shall be **monitored by an external auditor**.
TPD Art. 15(8)(3)	Member States shall ensure that the Commission, the competent authorities of the Member States, and the external auditor **have full access to the data storage facilities**. In duly justified cases the Commission or the Member States may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and

	national law.
TPD Art. 15(9)	The data stored shall not be modified or deleted by an economic operator involved in the trade of tobacco products.
TPD Art. 15(10)	Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.
FCTC Protocol Art. 9(5)(a)	All records shall be maintained for a period of at least four years.

Table 2: Requirements from the TPD and FCTC Protocol that are applicable to the data storage

For the purpose of this report, the events transmitted to the data storage solution are assumed to include information about the unit packet itself and also about the aggregation levels of packaging (i.e. unit packet to carton, carton to mastercase, and mastercase to pallet). Reporting data related to the aggregation levels will imply a lower volume of data to transmit and store. For instance, if the movements are reported at mastercase level, the report would only include the reference to around 500 unique identifiers contained in the mastercase[7], without specifying the information contained in the unique identifier. The unit packet level will always be tracked, because the mastercase level may be broken down at any point in the process.

According to the information needs specified by the TPD, two **data categories** shall be transmitted and recorded:

- **Traceability data**, which includes the following information:
    - The unique identifier of the unit packets, which shall include the elements of information referred to in Art. 15(2)(a) to Art. 15(2)(h).
    - The entry, intermediate movements and final exit of all unit packets into the possession of any economic operator involved in the trade of tobacco products, as referred in Art. 15(5). Each shipment movement implies a transfer of ownership of the tobacco products that shall be reported in order to be able to determine the actual shipment route from manufacturing to the first retail outlet. Art. 15(2)(i) refers the relevant information to be reported (i.e. date, destination, point of departure and consignee).
- **Trade data**, which is referred to in Art. 15(2)(j) and Art. 15(2)(k) as the trade information involved in any transaction (i.e. purchaser, invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet).

These data categories shall be **reported as events including time-stamp information**, which helps establish a consistent chronological order to facilitate surveillance activities. This is of paramount importance because the inherent nature of the Tracking and Tracing System is distributed, and the transmission of data from remote sources (i.e. manufacturers, importers, wholesalers or distributors) may not be done in real-time. As such, events may be not received in the data storage solution in the same temporal order in which they occurred.

Moreover, these data categories shall be based on open and mature standards such as **ISO/IEC 19987:2015 EPC Information services** (ISO/IEC 19987:2015 EPCIS, 2016).

[7] A mastercase contains 50 cartons, and each carton contains 10 unit packets.

Currently, this standard is widely used in several industry sectors to share data. It specifies an abstract and extensible data model to exchange supply chain specific data (i.e. trade and traceability information). This standard does not dictate the design or implementation of any data repository and is based on the EPC Information System (EPCIS) GS1 standard version 1.1 (GS1 EPCIS, 2014).

As a basic principle, any data storage model shall be **based on open and widely adopted standards** to ensure **interoperability**, allow for competitive and **cost-effective** alternatives, and promote the **re-usage** of open and proven industry technologies to the greatest extent possible. Thus, not only the data exchanged should be based on such standardisation principles, but also the interfaces and communication channels.

As it clearly emerges from the TPD provisions, a data storage solution shall store all relevant data and support the functioning of the Tracking and Tracing System.

Finally, this study recommends establishing a Data Governance Group, which aims at planning, monitoring and enforcing data related matters. The Data Governance Group should exercise control over the data management processes methods and define the minimum data integrity rules that assure the quality of data and help conduct surveillance activities.

1.1.2.1. Centralised model

In this model (B1), there is an **independent centralised data storage solution at EU level**. The centralised model comprises a single data storage solution, which shall include all the components needed to realise the capabilities required by the TPD.

The logical components of the centralised model are depicted below:

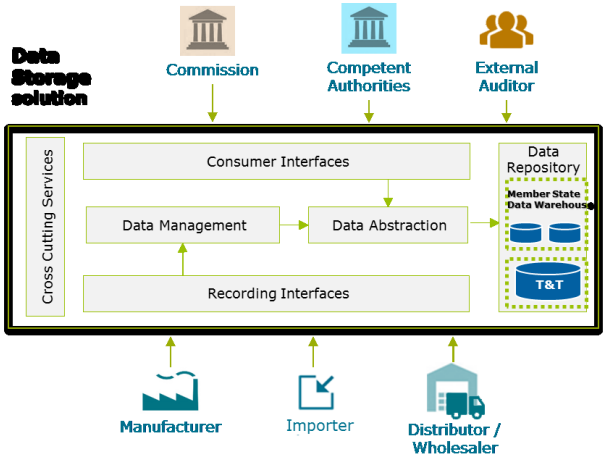


Figure 5: B1) Centralised model – high level logical components

The descriptions of the logical components are as follows:

- **Recording interfaces**. Group of components that expose secure interfaces, which facilitate the recording of all relevant data. These components are designed to respond efficiently in order to minimise the impact on the systems of the economic operators that transmit the tobacco products records. A positive acknowledgement of the message reception is returned, in order to indicate that

the message has been successfully accepted (i.e. non-repudiation). If there is an error or the message is rejected, a negative acknowledgement is returned.

- **Data management**. Group of components that process data prior to storage, aimed at **ensuring data integrity** by guaranteeing the completeness, consistency, accuracy and reliability of the data. As such, the following integrity constraints are enforced:
    - **Default integrity constraints**: Primary keys, entity integrity, foreign keys and referential integrity.
    - **Specific integrity constraints**: Format compliance, discrepancy between unique identifiers of the unit packets of tobacco products, consolidation of re-packaging events, consolidation of reverse logistics information, consolidation of aggregation information, coherence of the logistics information included in the report (e.g. when a reception event is received, check firstly if the dispatch event related to that transaction has been already received and secondly whether it informs about that transaction, etc.), management of information received in a non-temporal order (i.e. when the data storage solution receives an out of sequence event, the event is stored but will not be consolidated until the missing event arrives, etc.). The enforcement of the integrity constraints will be monitored by the Data Governance Group. Since various data integrity issues may arise with different priorities and potential actions to be carried out (e.g. confirm received data, verify inconsistent logistic information, etc.), it will be necessary to use a flexible notification engine where notifications related to these integrity checks can be configured. If data cannot be consolidated because integrity issues arise, it will be buffered internally, waiting for either an approval or the reception of missing information.
- **Data abstraction**. Group of components providing data access objects to persist and retrieve data. This allows decoupling from the physical data system implementation.
- **Consumer interfaces**. Group of components exposing secure interfaces that grant access to all relevant data in order to obtain and exploit a consolidated logical view of the tobacco products movements. A set of generic surveillance services will be made available to provide different means of access to data. These generic surveillance services could be extended by the competent authorities on a voluntary basis to interface with their national systems according to their needs. This approach has already been adopted by international systems such as the TRITON system where each country interfaces with a NATO central maritime control system in order to access data and services needed for their military purposes (NATO NCI Agency, 2014). The data capabilities that will be made available by these generic surveillance services are the following:
    - Dashboard with key indicators.
    - Reporting tool to facilitate the production of customised reports.
    - Alert tool to notify about patterns that have been detected. This tool will allow setting business rules to determine parameters when rules such as event submission are non-compliant. It operates as an 'exception

management' mechanism and optimises the involvement of competent authorities based on risk.

- Query tool to request information by applying different criteria.
- Business analytics applications.
- Bulk data extraction to allow exporting data.
- Application Programming Interface (API) to facilitate integration with other external systems such as the FCTC global information-sharing focal point system.
- Specific interfaces to integrate with systems of key external users (i.e. EMCS and SEED).

It should be noted that any request of data (e.g. specific product information or complex queries about different criteria) would be very efficient because the results are retrieved from a local indexed repository.

- **Data Repository**. Group of physical data storage components. The following considerations should be taken into account at the design stage:
  - In order to scale properly and deliver an optimum performance, the implementation of the physical repositories should follow different strategies. A widely adopted best practice (Tate & al., 2016) (European Commission - JRC, 2016) (O'Reilly, 2016) (Amazon web services, 2016) for large scale systems to establish separate physical data storage areas according to the project needs and priorities, such as frequency of access (e.g. the most frequently accessed data should be stored in the faster storage tiers), age of data, protection, or specific business rules. Therefore, such a **tiered storage approach** can deliver the required combinations of performance, capacity and resilience. Two tiers of data are recommended at minimum: a "*hot*" tier with short response times and a "*cold*" tier with longer response times. When required, data could be moved between tiers automatically.
  - In addition of providing a global comprehensive view of all the relevant data, the Data Repository should make it possible to have different **data warehouses per Member State** on a voluntary basis, which provides flexibility by allowing access to a sub-set of the complete data (e.g. data related to tobacco products sold in a specific Member State, or data related to products manufactured in a specific Member State, etc.) in a unified and transparent way without needing to copy and duplicate the original data. This allows the competent authorities to have their own data warehouse as a "virtual database" in order to facilitate law enforcement at national level.
  - The data retention period is four years at minimum, as required by the FCTC Protocol. The final solution will be designed taking into account the highest data retention period required by Member States (e.g. Austria requires 10 years).
- **Cross-cutting services**. Group of components aimed at providing cross-cutting services such as security, configuration, administration, monitoring, personal data management and notifications.

For an independent centralised data storage solution at EU level, the following considerations should be taken into account:

- This model assumes the tender and selection of the independent centralised data storage solution at EU level. The identification of the entity responsible for the selection and the procedure to be followed must be carefully analysed in light of Article 15 of the TPD.
    - A contract with this independent third party data storage provider must be concluded by each of the manufacturers and importers.
    - The independence and technical capabilities of the third party data storage provider, as well as the contracts concluded with the manufacturers and importers, shall be approved by the Commission.
    - The facilities of the data storage provider must be located in the European Union.
- This model poses the challenge of being a single point of vulnerability, meaning that, in case of disruption of this central solution, the updating of information by the industry and all the economic operators within the supply chain would be untracked and untraceable (totally, or at least, not in real time).
- A high risk of monopoly exists because there is a single data storage provider that establishes the data storage solution.
- The third party data storage activities shall be monitored by an external auditor, proposed and paid by the manufacturers and approved by the Commission.
- The data storage solution shall be designed to efficiently support the storage of and access to all relevant data, taking into account the constraint that the data sizing requirements of the whole Tracking and Tracing System shall be supported by this single solution.

Finally, some examples of European systems with a central data repository are listed below:

- TRACES (TRAde Control and Expert System) (European Commission - TRACES, 2016). TRACES facilitates the exchange of information between all involved trading parties and control authorities and speeds up the administrative procedures. TRACES enables the possibility to trace back and forth all the movements of animals, semen and embryos, food, feed and plants.
- The Schengen Information System (SIS) (European Commission - DG HOME, 2016). SIS is a highly efficient large-scale information system that supports external border control and law enforcement cooperation in the Schengen States.

1.1.2.2. Decentralised model per manufacturer/importer

This model (B2) comprises a **group of independent data storage solutions per manufacturer/importer**, where each storage solution hosts data exclusively related to a specific manufacturer/importer. An **independent central Federation Services solution at EU level** offers central services, necessary to provide logical access to the data spread across different data storage solutions.

The responsibilities of the independent central Federation Services solution are twofold:

a) To implement communication with the different decentralised data storage solutions, in order to provide a comprehensive logical view of tobacco products movements regardless of where data is located.

b) To provide a single secure point for seamlessly routing event notifications from the distributors and wholesalers to the appropriate data storage solution.

This model allows for a data storage solution to be either exclusive for a single manufacturer/importer or to be shared by a specific group of manufacturers/importers. Moreover, each data storage solution is autonomous and manages its own database, where solely data related to a specific (or group of) manufacturer(s)/importer(s) is stored.

It should be noted that the concept of "groups" is not specifically indicated in Article 15(8) of the TPD. For this approach to be deemed acceptable and compliant with the TPD, a hosting provider that stores data on behalf of multiple manufacturers and importers will be required to:

- Segregate access to data belonging to different companies, in order to preserve commercially sensitive information of each manufacturer or importer separate (Article 15(8) of the TPD).
- Separate data related to the Tracking and Tracing System from other data of the same company (Recital 31 of the TPD).

The logical components of this model are depicted below:

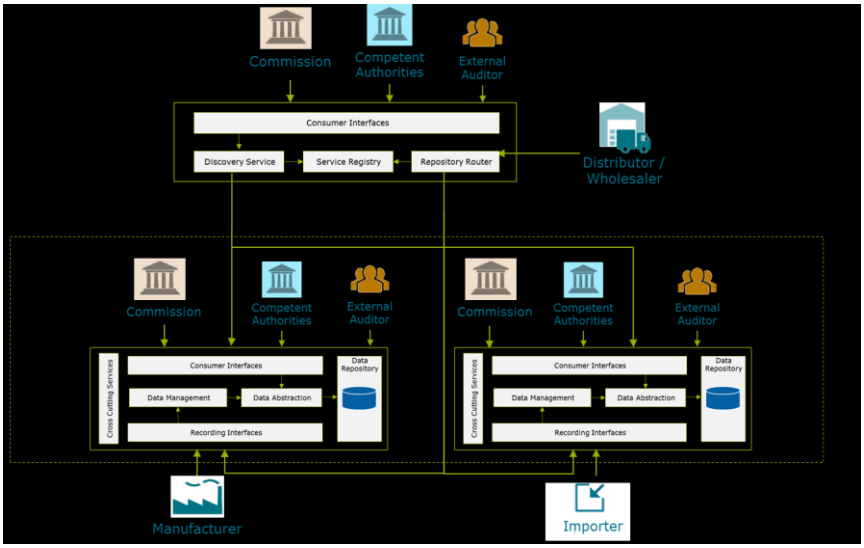


Figure 6: B2) Decentralised model per manufacturer/ importer – high level logical components

The descriptions of the logical components are as follows:

- **Federation Services solution**. An independent and autonomous solution that includes the following components:
    - **Discovery service**. It provides a single logical access point to the data of the Tracking and Tracing System. The default approach to realise a generic query request would be to forward the query to each of the data storage solutions, wait for the individual results, and merge the collected data. This is because the Federation Services solution does not locally store

traceability or trade data. However, when requesting specific information related to a certain manufacturer or product, the Discovery Service only has to forward that request to the data storage solution that hosts the data and no additional queries must be forwarded to the other repositories. Hence, simple specific queries (i.e. retrieval of product, manufacturer or importer information) are performed quite efficiently, but complex queries with additional criteria (e.g. considering locations, data and time, trade information, etc.) are performed less efficiently, because they must be forwarded to the data storage solution. Since the occurrence of illicit trade is cross-border and the main type of fraud that can be detected by the Tracking and Tracing System is the diversion of shipments, it can be anticipated that the surveillance queries would be complex rather than based on simple specific criteria.

  - **Service Registry**: It manages the registry of locations of the distributed systems. This connectivity information is stored in an internal database. When a new data storage solution is established, its location must be configured in the Service Registry to notify the Discovery Service about the availability of a new data source.
  - **Repository Router**: It is responsible for routing the traceability and trade events reported from the distributors and wholesalers to the proper target storage. It provides a single secure point for seamlessly routing and decoupling the client reporting systems of information regarding the data storage solution locations. Based on the information included in the message and the storage solution locations managed by the Service Registry, this component is able to identify the appropriate data storage solution to route the message to. As a first approach in this particular model, the decision on storage location could be based on the following rule: if the tobacco product has been manufactured within the European Union, then the manufacturer name will be used; otherwise the importer name will be used.
  - **Consumer Interfaces**. This group of components exposes secure interfaces that grant full access to the traceability and trade data in order to obtain a consolidated view of the tobacco products movements.

- **Data storage solution**. It is an independent and autonomous solution that includes the same components as the centralised model, with the exception of the Data Warehouse capability. The data stored is only related to a specific (or group of) manufacturer(s)/importer(s). The data retention period is the same as in the B1 model, which is four years at minimum.

With the aim of minimising the requirements of the central Federation Services solution, the possibility could be further analysed that some federation specific services (e.g. Repository Router or Service Registry) be provided by the data storage solutions themselves. This could allow for communication savings to the distributors and wholesalers.

When having an independent decentralised model per (or group of) manufacturer(s)/importer(s), the following considerations must be taken into account:

- In this model, in addition to the data storage itself, a central Federation Services solution is necessary to orchestrate the access to the data spread across the group of data storage solutions. As such, the following points should be noticed:
    - This solution shall be established by an independent third party solution provider.
    - This option assumes the tender and selection of the independent central Federation Services solution at EU level. The identification of the entity responsible for the selection and the procedure to be followed must be carefully analysed in the light of Article 15 of the TPD.
- In this model, the risk of monopoly is low because it is expected that several providers will be able to offer implementations of data storage solutions.
- All the systems involved shall be designed to efficiently support the storage and access to all relevant data, taking into account the constraint that data is actually spread between distributed data storage solutions.

Finally, as an international example with a similar storage model, Brazil's system for tracking and tracing medications (Rx-360 Consortium, 2014) should be mentioned. This system has storage per supply chain member where all the product information, movements and shipment data are stored. This logical partitioning of the data per supply chain member could be compared with the manufacturer/importer partitioning criterion of B2.

1.1.2.3. Decentralised model per Member State

This model (B3) comprises a **group of independent data storage solutions per Member State**, where each storage solution hosts data exclusively related to a certain country. An **independent central Federation Services solution at EU level** offers the central services necessary to have logical access to the data, which is spread across different data storage solutions.

The main difference between this model and the B2 model – decentralised per manufacturer/importer – is that the criteria used to distribute data between the data storage solutions is the Member State. As a first approach, the identification of the reference country for the storage location could be based on the place of manufacture / first entry into the EU market. Another additional or alternative criteria could be the Member State where the product will be marketed. However, it should be noted that the supply chain of tobacco products is transnational, thus the storage and retrieval of data could be more complicated than in B2.

Since this option also deals with data spread across different data storage solutions, it is necessary, as in the B2 model, to include a single Federation Services solution.

This model allows for a data storage solution to be either exclusive for a single Member State or to be shared by a group of Member States. Moreover, each data storage solution is autonomous and manages its own database where only data related to a specific (or group of) Member State(s) is stored.

A hosting provider that stores the data of multiple manufacturers and importers will be required to:

- Segregate access to data belonging to different companies, to keep the commercially sensitive information of each manufacturer or importer separate.
- Separate data related to Tracking and Tracing System from other data of the same company.

The logical components of this model are depicted below:

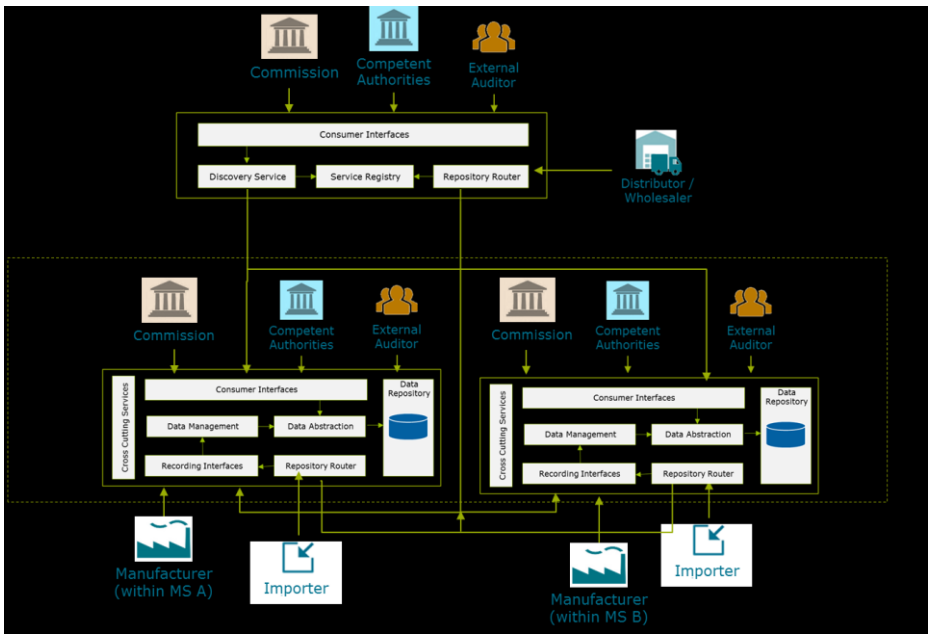


Figure 7: B3) Decentralised model per Member State – high level logical components

The descriptions of the logical components are as follows:

- **Federation Services solution**. It is an independent and autonomous solution that includes the same components as the Federation Services solution in the B2 model, but with the following difference:
  - The Routing Service component is accessed by the distributors and wholesalers.
- **Data storage solution**. It is an independent and autonomous solution that includes the same components as the B1 model, with the exception of the Data Warehouse capability, and additionally the Repository Router component. This is because, in this model, importers need to access different repositories, depending on which country they are importing products to. The data stored is only related to products manufactured in or imported to a specific (or group of) Member State(s). The data retention period is the same as the B1 model, which is four years at minimum.

With an independent decentralised model per Member State, the following considerations must be taken into account:

- In this model, in addition to the data storage itself, a central Federation Services solution is necessary to orchestrate access to the data, which is spread across the group of data storage solutions. As such, the following points should be noted:
  - This solution shall be established by an independent third party solution provider.

  - This option assumes the tender and selection of the independent central Federation Services solution at EU level. The identification of the entity responsible for the selection and the procedure to be followed must be carefully analysed in the light of Article 15 of the TPD.

- Each data storage solution is established by an independent third party data storage provider.
  - A specific (or group of) Member State(s) will select an independent third party data storage provider and conclude a contract with this provider to establish a data storage solution.
  - Within each data storage solution, the independent third party data storage provider activities shall be monitored by an external auditor. Annual reports of the external auditors shall be submitted to the competent authorities and the Commission.
- In this model, the risk of monopoly is low because it is expected that several providers will be able to offer implementations of data storage solutions.
- All the systems involved shall be designed to efficiently support the storage of and access to all relevant data, taking into account the constraint that data is actually spread between distributed data storage solutions.

Finally, as an example of a European system with repositories at Member State level, the implementation of the Falsified Medicine Directive should be mentioned. Its Delegated Act (European Commission - Delegated Act FMD, 2015) requires that each country operates its own repository, which will hold serialisation data of all the medicine products in its supply chain. The Delegated Act allows for repositories to serve the territory of only one Member State (namely 'national repositories') or the territory of multiple Member States (namely 'supranational repositories'). This logical partitioning of the data at a national level could be compared with the Member State partitioning criterion of B3.

1.1.2.4. Combined model: centralised for surveillance and decentralised for recording per manufacturer/importer

This model (B4) comprises an **independent central surveillance solution at EU level** and a **group of independent data storage solutions per manufacturer/importer**.

The envisaged scale of the data to be handled by the Tracking and Tracing System, the fact that the events reported by the economic operators may be not notified in the same temporal order as they occur, and that the consolidated data shall be made available to the competent authorities with the minimum delay, were factors that led to the proposal of this combined model. It integrates benefits from the centralised (i.e. efficient access to the comprehensive logical view of data) and the decentralised (i.e. efficient data processing and writing) models.

Hence, the aim of this model is to decouple read accesses from write accesses, splitting such responsibilities between the following solutions:

- The **data storage solutions**, which behave as **intermediate layers focused on data recording, processing and storing**. Each data storage solution processes data exclusively related to a certain (or group of) manufacturer(s)/importer(s), which is later synchronised with the central surveillance solution. As such, with

this distributed topology, the data accesses necessary to conduct the data management activities to assure data integrity are made within the distributed and autonomous data storage solutions themselves, without impacting the central repository hosted within the surveillance solution. Once the data is successfully consolidated, it is synchronised with the surveillance solution with the minimum delay.

- The independent central **surveillance solution**, which offers a **comprehensive logical view** of all relevant data based on a local data storage solution with data that has been synchronised previously from the distributed data storage solutions.

The main differences with B2 are related to the capabilities that ensure effective functioning of the Tracking and Tracing System when used by the competent authorities to fight illicit trade:

- The surveillance solution has a local storage that provides a **higher level of data readiness** for the competent authorities in comparison with B2. Complex queries (e.g. considering locations, data and time, trade information, etc.) would perform less efficiently in B2 than in B4, because these queries must be forwarded to all the data storage solutions. As mentioned, it can be anticipated that the surveillance queries would be complex rather than based on simple specific criteria. This lack of efficiency when accessing data in B2 could worsen as the volume of data increases.
- The surveillance solution offers the additional possibility of having **data warehouses per Member State** on a voluntary basis that provides flexibility by allowing access to a sub-set of the data (e.g. data related to all tobacco products sold in a specific Member State, or data related to products manufactured in a specific Member State, etc.) in a unified and transparent way without having to copy and duplicate the original data. This capability facilitates **enforcement by the competent authorities** because each Member State could have its own data warehouse, configured according to national rules and needs.

As in B2 model, this model allows for a data storage solution to be either exclusive for a single manufacturer/importer or shared by a specific group of manufacturer(s)/importer(s). Moreover, each data storage solution is autonomous and manages its own database where only data related to a specific (or group of) manufacturer(s)/importer(s) is stored.

As in B2, it should be noted that the concept of "groups" is not specifically indicated in Article 15(8) of the TPD. For this approach to be deemed acceptable and compliant with the TPD, a hosting provider that stores data on behalf of multiple manufacturers and importers will be required to:

- Segregate access to data belonging to different companies, to preserve commercially sensitive information of each manufacturer or importer separate (Article 15(8) of the TPD).
- Separate data related to the Tracking and Tracing System from other data of the same company (Recital 31 of the TPD).

The logical components of this model are depicted below:

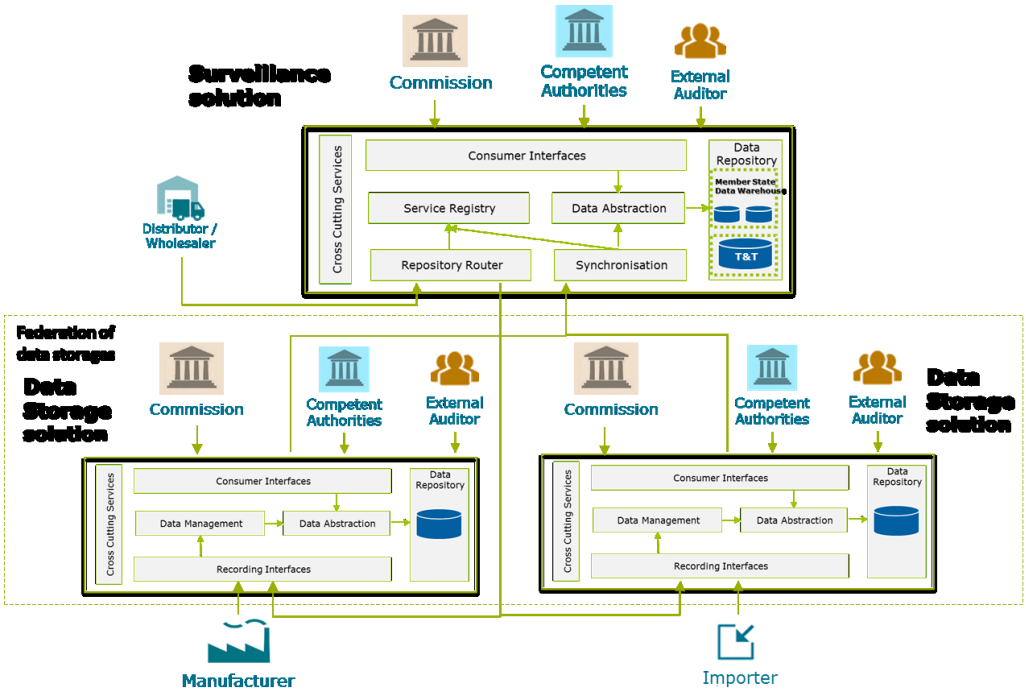


Figure 8: B4) Combined model: centralised for surveillance and decentralised for recording (per manufacturer/ importer) – high level logical components

The descriptions of the logical components are as follows:

- **Surveillance solution**. It is an independent and autonomous solution, which is comprised of the following components:
    - Synchronisation. Group of components that receives data from the data storage solutions, which needs to be synchronised and consolidated with the complete tracking and tracing database.
    - Repository Router. Group of components with the same capabilities as in the B2 model.
    - Service Registry. Group of components with the same capabilities as in the B2 model.
    - Consumer Interfaces. Group of components with the same capabilities as in the B1 model.
    - Data Repository. Group of components with the same capabilities as in the B1 model. Here, it should be noted that, in addition to having access to all tracking and tracing data, this component offers the possibility of having data warehouses per Member State. These allow the competent authorities to have their own data warehouses in order to facilitate their national enforcements.
- **Data storage solution**. It is an independent and autonomous solution, which includes the same components as the B2 model, but with the following differences:

  - Consumer Interfaces. Group of components with the same capabilities as in the B2 model, but also providing secure synchronisation capabilities with the surveillance solution.
  - Data Repository. Group of components with the same capabilities as in the B2 model.

With a combined model, the following considerations must be taken into account:

- The central surveillance solution provides a comprehensive traceability view, based on the data from the different data storage solutions that have been previously synchronised.
- In this model, in addition to the data storage itself, a central surveillance solution is necessary to orchestrate access to the data, which is spread across the data storage solutions. As such, the following points should be noted:
  - This solution shall be established by an independent third party data storage provider.
  - This option assumes the selection of the independent central surveillance solution at EU level. The identification of the entity responsible for the selection and the procedure to be followed must be carefully analysed in light of Article 15 of the TPD.
  - A contract, with this single independent third party data storage provider, must be concluded by each of the manufacturers and importers.
  - The independence and technical capabilities of the third party data storage provider, as well as the contracts concluded with the manufacturers and importers, must be approved by the Commission.
- Each data storage solution is established by an independent third party data storage provider.
  - A specific (or group of) manufacturer(s)/importer(s) will select an independent third party data storage provider and conclude a contract with this provider to establish a data storage solution. The independence and technical capabilities of the third party, as well as the contracts concluded, must be approved by the European Commission.
  - Within each data storage solution, the independent third party data storage provider activities shall be monitored by an external auditor. Annual reports of the external auditors must be submitted to the competent authorities and the European Commission.
- In this model, the risk of monopoly is low because it is expected that several providers will be able to offer implementations of data storage solutions.
- All the systems involved shall be designed to efficiently support the storage of and access to all relevant data, taking into account that the data sizing requirements of the whole Tracking and Tracing System shall be supported by the central surveillance solution.

1.1.3. Allowed data carriers

This analysis aims at describing the allowed set of data carriers (approved by the competent authorities) without selecting any specific data carrier. The data carrier(s) will contain the unique identifier 1) per unit packet; and 2) per aggregation packaging level.

1.1.3.1. Identification levels

The defined identification levels represent the categories that group the unit packet and the aggregation packaging levels.

The definition of the options in this analysis is conditioned by the amount of information required for each identification level.

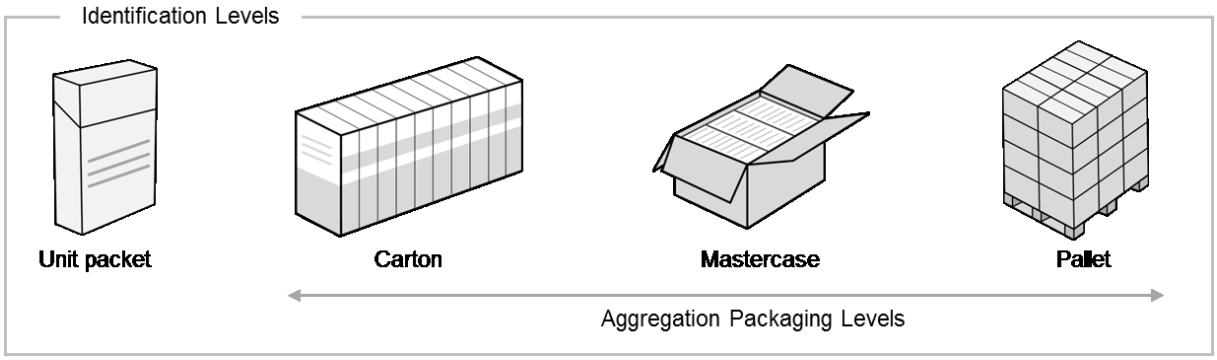


Figure 9. Description of identification levels

The unit packet is the smallest individual packaging of a tobacco or tobacco related product that is placed on the market. The aggregation packaging levels allow for the association of tobacco products, thus facilitating their transportation, management and storage. The three levels of aggregation identified by the TPD are: carton, mastercase and pallet, although further aggregation levels such as containers could be considered in future analyses.

Initial estimations, based on the analysis conducted in the context of Interim Report I, suggest that a unique identifier of maximum 161 characters would be necessary (everis, 2016) to contain the information required under Article 15(2) of the TPD. However, the final content of the unique identifier at unit packet level has been specified in Work Package 3 and summarised in Annex II. Indeed, it has been possible to reduce the size of this unique identifier by taking into account the following available mechanisms: usage of look-up tables for some fields, combining of some fields into one (or group of) company specific field, or creation of new standard traceability fields fully compliant with TPD requirements.

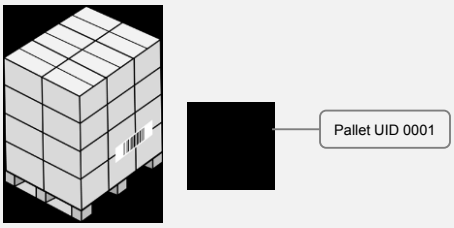
The generation of the unique identifier for the unit packet level will be based on open standards in order to assure the interoperability and integrity of data. As the information requested by Article 15 of the TPD may contain detailed information from the manufacturers and importers operations, this study proposes that the unique identifier for the unit packet level should be previously transformed into encrypted digits, thus preventing public visualisation of the contained information.

The TPD requires all economic operators in the supply chain to record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets. This obligation is addressed by the marking and recording of aggregation packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

The aggregation packaging levels usually contain data carriers to facilitate logistic activities, and they are established by the economic operators. It must be clarified that the identifier for the aggregation packaging levels is conceived as an independent data carrier that contains all the information requested for its unique identification. As with the unit packet level, the generation of the unique identifier for aggregation packaging levels will be based on open standards.

The unique identifier for aggregation packaging levels will be recorded in the Tracking and Tracing System and the unique identifier (UID) of each item contained within it (in a parent-child hierarchy). For example, a carton's UID is linked to the UIDs of the 10 unit packets contained within it, facilitating traceability across the supply chain.

The unique identifier permits the identification in the Tracking and Tracing System of all the grouped items, and contributes to the efficiency of all the scanning tasks through all the economic operators' activities.



Unit Packet	Carton
Unit Packet UID 00001	Carton UID 0001
Unit Packet UID 00002	
⋮	
Unit Packet UID 00009	
Unit Packet UID 00010	

Carton	Mastercase
Carton UID 0001	Master case UID 0001
Carton UID 0002	
⋮	
Carton UID 0024	
Carton UID 0025	

Mastercase	Pallet
Mastercase UID 0001	Pallet UID 0001
Mastercase UID 0002	
⋮	
Mastercase UID 0024	
Mastercase UID 0025	

The study presented below describes what type of information is contained in the data carrier for aggregation packaging levels and estimates its length to a maximum of 25 characters. This study presents an example of how to estimate the maximum number of characters needed for the unique identifier in aggregation packaging levels. However, its creation will be addressed in the Interim Report III. All identification fields to be contained in the unique identifier can be included by using open standards (GS1 Barcodes, 2017). It is not foreseen to encrypt the information contained in the data carriers for aggregation packaging levels, as it will not contain any sensitive information.

In order to estimate the number of digits needed to create the unique identifier, the consumption of tobacco in Europe and a timeframe of 100 years[8] of use is considered. The following table presents the consumption of unit packets and aggregation packaging levels of cigarettes in Europe for the year 2015.

Consumption of Tobacco Products in Europe. Year 2015	
Cigarettes - Unit Packets	26.600.000.000
Cigarettes – Cartons	2.660.000.000
Cigarettes - Mastercases	53.200.000
Cigarettes – Pallets	1.064.000
Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features, Final Report	

The number of digits dedicated to identifying each item should take into consideration the total consumption for that aggregation level.

As stated before, this study does not propose an alternative to generate the UID; it just estimates by means of examples the maximum required length.

In the example below, the UID includes:

- Identifier of type of aggregation level - 1 digit
- Unique identifier – 7 alphanumeric characters
- Year of expedition – 2 digits
- Control digit – 1 digit
- New categories may arise in the following work packages

Consequently, after including a safety buffer in view of further analysis, it could be concluded that the unique identifiers for the aggregation packaging levels require a maximum length of 25 characters.

Before selecting the allowed types of data carrier for the unit packet and the aggregation packaging levels, the traceability systems used in several industries were reviewed. The selection process of these data carriers can be adjusted to different criteria such as the information requested, the adaption to production lines or the physical limitations of the package.

The revision of the following industries enabled a better understanding of the different solutions in use, and identification of those that can best adapt to the requests of this study.

Industry / Sector	Data Carriers used for traceability activities and control
Pharmaceutical	Data Matrix at unit packet level (Infosys, 2014) GS1-128 for transportation and logistics (GS1 Pharmaceutical, 2016)
Explosives	Data Matrix, barcode or alphanumeric format (European

[8] The team has estimated a time horizon of 100 years to estimate the number of digits requested for the unique identifier of aggregation packaging levels.

	Commission - EU Directive 2008/43/EC - Traceability of explosives, 2008)
Tobacco Industry	DotCode (European Commision - Targeted stakeholder consultation TPD, 2015)
Food and Beverages	GS1-128 (GS1 Traceability for Fresh Fruits and Vegetables, 2015)
Transportation and logistics	SSCC number using EAN/UPC, ITF-14 or GS1-128 (GS1 Logistics Label, 2016)

Table 3: Data carriers per industry

1.1.3.2. Assumptions

The identification of the allowed data carriers should take into consideration:

- For the unit packet: due to space limitations, it can only contain a single data carrier.
- For the aggregation packaging levels: it will be considered that there are no space limitations where several data carriers could be contained.

The uses of the data carrier in the aggregation packaging levels is conceived to facilitate the reporting of the following events:

- Aggregation (a number of items are grouped and identified with a unique identifier, i.e. ten unit packets are grouped into a carton)
- Disaggregation (the aggregation packaging level is separated into items, i.e. a pallet is separated into 50 mastercases)
- Entry, exit and intermediate movements through the whole supply chain.

Based on the previous table and the stakeholder consultation, it can be stated that:

- The 1D data carriers are not able to contain the unique identifier at the unit packet level, due to the space limitations and the amount of information requested by Article 15 of the TPD.
- Dot Code is the only data carrier that can be printed at the same pace than high speed production lines.
- 1D data carriers are the best alternative for the aggregation packaging levels involved in the logistic process, due to the availability of linear barcode scanners along the distribution chain.

1.1.3.3. Options

Based on the conclusion of the Inception Impact Assessment, five options have been identified:

- **Option C1:** System with a single data carrier for all identification levels.
- **Option C2:** System with a single data carrier per identification level and optional data carriers for aggregation packaging levels.
- **Option C3:** System with a limited variety of data carriers per identification level.

- **Option C4:** System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels.
- **Option C5:** Free system allowing any existing approved data carrier.

Options C3 and C4 consider a limited variety of data carriers per identification level. The team has estimated a range of approximately four possible types of data carriers per identification level for these options. The different types of data carrier will be selected in order to facilitate adaptation to economic operators' operations.

All options allow for the inclusion of all information requested by Article 15 of the TPD at all levels of identification. The selection of the data carriers for each identification level takes place in Interim Report III.

1.1.3.3.1. System with a single data carrier for all identification levels

This option uses the same data carrier for the unit packet and all the aggregation packaging levels.

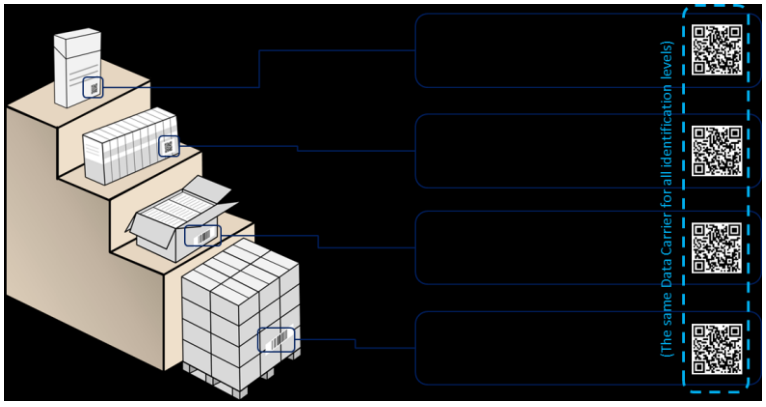


Figure 10. Description of the system with a single data carrier for all identification levels[9]

In this option, the same data carrier is printed or affixed in all the unit packets of tobacco products and their aggregation levels.

This option has implications for three groups of stakeholders:

- Manufacturers and importers:
  - They have to print or affix the selected type of data carrier in the unit packets and aggregation packaging.
  - The selection of a unique type of data carrier may affect the processes of printing, affixing and verifying in the production lines, due to their ability to adapt to the production speed, provoking disruptions in the production line.
- Wholesalers and distributors:

[9] All the data carriers symbolized in the Figures 9, 10, 11, 12 are only a representation for the better understanding and they are not intended to represent the final selection. Further consideration of available data carriers will be set out in the next work package.

- They have to adapt their scanning devices to be able to scan the data carrier included in the aggregation levels.
- The selection of a unique type of data carrier avoids the use of 1D data carriers for the aggregation packaging levels. The linear scanners that read 1D barcodes, the most common reading devices in the distribution chain, cannot be used. Therefore, a different type of scanner is needed for the distribution chain operators to correctly scan the unique identifiers for aggregation packaging levels.

- Competent authorities:
  - They must be equipped to read the data carriers included in the unit packet and the aggregation packaging levels.
  - As only one data carrier is allowed, the scanning device for competent authorities will only need to scan one data carrier (easier than the other options).

1.1.3.3.2. System with a single data carrier per identification level and optional data carriers for aggregation packaging levels

This option uses a single, but potentially different per identification level, data carrier for the unit packet and all the aggregation packaging levels. It also allows adding any approved data carrier for the aggregation packaging levels to facilitate the reading activities.

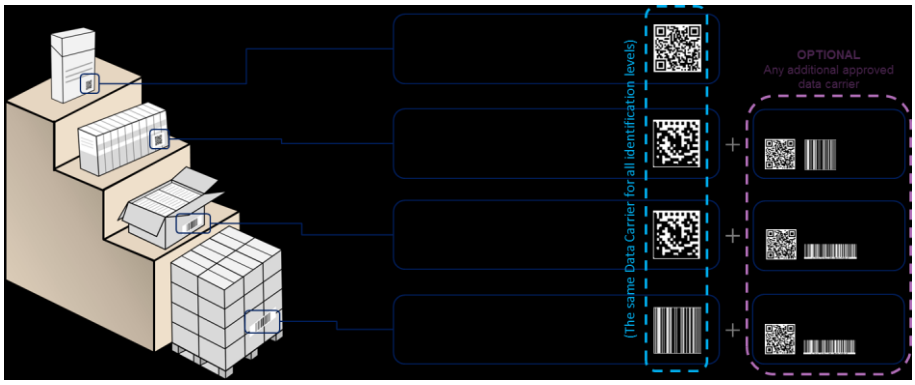


Figure 11. Description the system with a single data carrier per identification level and optional data carriers for aggregation packaging levels

In this option, one data carrier is printed or affixed in the unit packets of tobacco products, and one data carrier on each aggregation packaging level.

This option allows for the addition of optional data carriers for the aggregation packaging levels, containing the same information as the selected mandatory data carrier. This optional addition will facilitate scanning activities among the distribution chain operators by:

- Adding data carriers that are integrated in the distribution chain operator's activities.
- Adding RFID or NFC data carriers that can reduce the scanning time and increase the efficiency of the operations.

- Containing the same information as the selected mandatory data carrier.

The actions taken in this option have major implications for three groups of stakeholders:

- Manufactures and importers:
    - They are in charge of the printing or affixing activities of data carriers for the unit packets and the aggregation packaging levels.
    - As with Option 1, the selection of only a type of data carrier for the unit packets may disrupt processes in the production lines.
    - They can print or affix additional data carriers in the aggregation packages to facilitate the tracking and tracing activities of wholesalers and distributors.
- Wholesalers and distributors:
    - They are in charge of reporting the events of tobacco products along the distribution chain in accordance with the TPD.
    - The three aggregation packaging levels have a specific type of data carrier, which may or may not be equal. The distributors have to adapt their scanning devices to be able to scan the data carrier included in the aggregation levels. The selection of the data carrier will facilitate the adaptation to the distribution activities.
    - The optional addition of data carriers may enable the distributors to adapt their current installed base to them.
- Competent authorities:
    - They must be equipped to read the data carriers included in the unit packet and the aggregation levels.
    - They may require several scanning devices to be able to read all the allowed data carriers enabled for the identification levels.

1.1.3.3.3. System with a limited variety of data carriers per identification level

This option allows operators to choose between a variety of data carriers for the unit packet and the aggregation packaging levels. The data carriers for each identification level variety may differ.

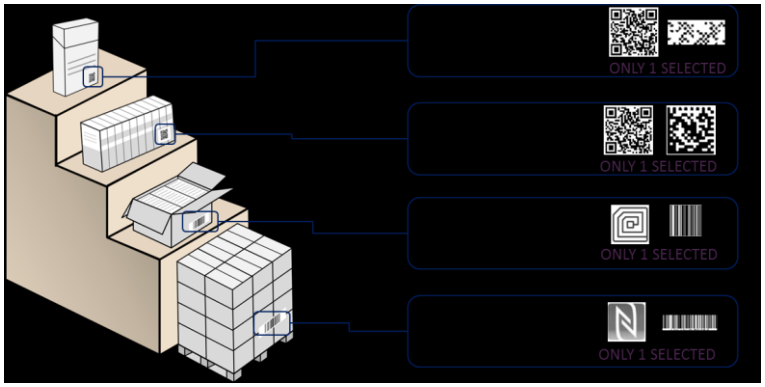


Figure 12. Description of the system with a limited variety of data carriers per identification level

In this option, one data carrier, selected from a limited set of allowed data carriers, is printed or affixed per unit packet and aggregation packaging level.

The actions taken in this option have major implications for three groups of stakeholders:

- Manufactures and importers:
    - They are in charge of selecting the data carrier that they are going to print or affix to the unit packet and the aggregation packaging levels. We foresee that this choice will be made in order to reduce impact on their manufacturing and distribution chain operations.
    - They are in charge of printing and affixing the data carriers to the unit packets and the aggregation packages.
- Wholesalers and distributors:
    - They are in charge of reporting the events of tobacco products along the distribution chain, in accordance with the TPD.
    - The three aggregation packaging levels have a variety of allowed data carriers, which could be different. The distributors have to adapt their scanning devices to be able to scan the allowed variety of data carriers presented in the aggregation packaging levels.
    - The selection of the variety of data carriers will be conceived in order to facilitate adaptation to the distribution activities.
- Competent authorities:
    - They must be equipped to read the data carriers included in the unit packet and aggregation packaging levels.
    - As a variety of data carriers is allowed, the scanning devices for competent authorities will have to read all the varieties of data carriers permitted per identification level.

1.1.3.3.4. System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging level

This option enables the economic operators to choose between a variety of data carriers for the unit packet and all aggregation packaging levels. The data carriers for each identification level may differ. It is also optional to add an approved data carrier for the aggregation packaging levels.

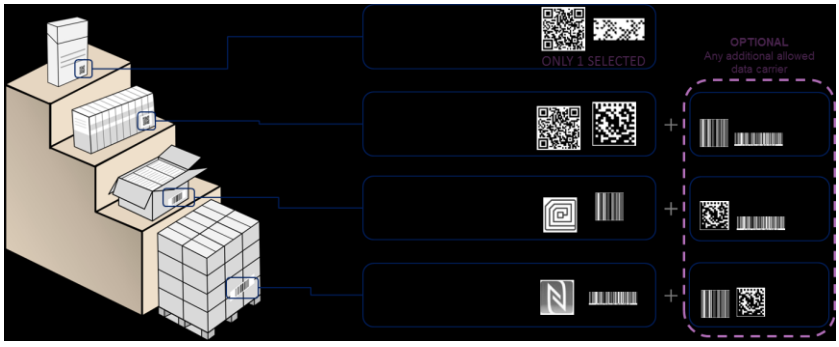


Figure 13. Description of the system with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels

In this option, one data carrier, selected from a limited set of allowed data carriers, is printed or affixed per identification level As with Option 2, this option enables the optional addition of data carriers to facilitate scanning activities among the distribution chain operators.

The actions taken in this option have major implications for three groups of stakeholders:

- Manufactures and importers:
    - They are in charge of the printing or affixing activities of data carriers for the unit packets and aggregation packaging levels.
    - It is assumed that the ability to choose from a variety of data carriers will reduce the impact on their manufacturing and distribution chain operations.
    - They can print or affix additional data carriers in the aggregation packages to facilitate the tracking and tracing activities of wholesalers and distributors.
- Wholesalers and distributors:
    - They are in charge of reporting the events of tobacco products along the distribution chain in accordance with the TPD.
    - The distributors must adapt their scanning devices to scan the allowed variety of data carriers presented in the aggregation packaging levels.
    - The optional addition of data carriers may enable distributors to adapt their current installed base to them, providing more flexibility.
- Competent authorities:
    - They must be equipped to read the data carriers included in the unit packet and aggregation packaging levels.
    - As with Option 3, the scanning devices for competent authorities will have to read all varieties of data carriers permitted per identification level.

1.1.3.3.5. Free system allowing any existing approved data carrier

This option enables the use of any previously approved data carrier and gives economic operators the autonomy to choose the data carrier that best fits their needs. The unit packet only contains one data carrier, whereas the aggregation packaging levels do not have any limitation, as with Options 2 and 4.

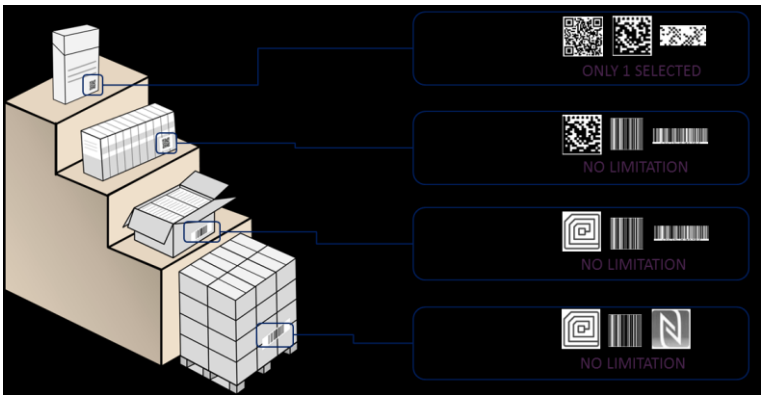


Figure 14. Description of the free system allowing any existing approved data carrier

In this option, one data carrier, selected from a set of approved data carriers, is printed or affixed per identification level. As with Option 2, this option enables the optional addition of data carriers to facilitate scanning activities among the distribution chain operators.

The actions taken in this option have major implications for three groups of stakeholders:

- Manufactures and importers:
  - They are in charge of the printing or affixing activities of data carriers for the unit packets and the aggregation packaging levels.
  - They can select any approved data carrier for each identification level, minimising the impact on their manufacturing and distribution chain operations.
  - They can print or affix additional data carriers on the aggregation packages to facilitate the tracking and tracing activities of wholesalers and distributors.
- Wholesalers and distributors:
  - They are in charge of reporting the events of tobacco products along the distribution chain in accordance with the TPD.
  - The distributors have to adapt their scanning devices to scan the data carriers presented in the aggregation packaging levels used by their providers. If their providers have printed or affixed additional data carriers, they can also adapt their scanners to them.
- Competent authorities:
  - They must be equipped to read the data carriers included in the unit packet and aggregation packaging levels.
  - As any previously approved data carriers is allowed, the scanning devices for competent authorities must be able to scan numerous data carriers (or competent authorities must have multiple devices to read all of them).

1.1.4. Allowed delays in reporting events

This section presents the options regarding the **allowed delays in reporting events**, which should ensure that traceability and trade data are transmitted to and recorded in the tracking and tracing data storage solution, within the maximum allowed time lag between the event occurrence and its effective report by the economic operator. As such, the *allowed delay* refers to the maximum time allowed to transmit the reports required by the TPD from the economic operator to the data storage solution. The chosen option must be implemented in a cost-efficient manner, meeting the defined primary and secondary requirements.

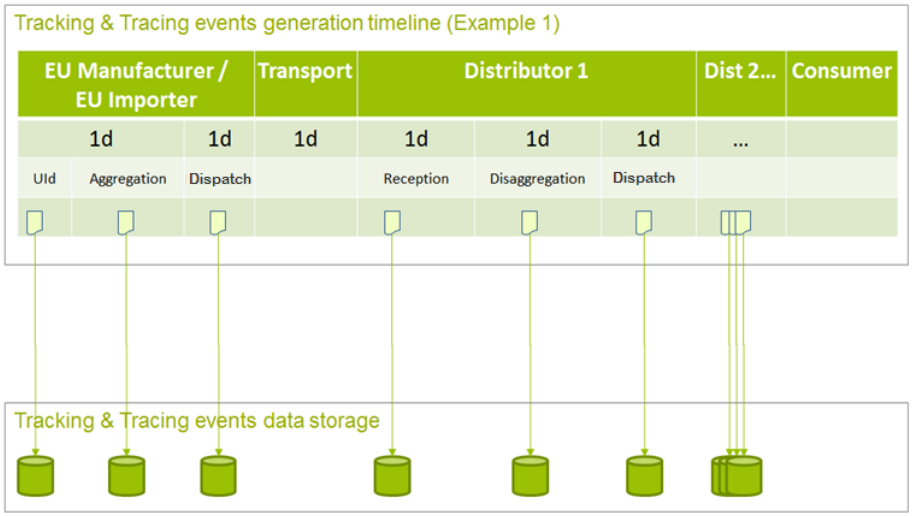


Figure 15: A conceptual view of the possible event sequence generation in a timeline

The timeline above depicts each economic operator generating and reporting events to the data storage solution.

The evaluation of distinct options for allowed delays is necessary because each delay will have a different impact on the industry when performing the event reporting. However, data freshness should always be driven by business requirements, not the technology itself (Lebdaoui, Orhanou, & Hajji, 2013, p. 1). Some economic operators may not actually support some of the given options for allowed delays, and one option may work more efficiently for some economic operators than for others. For instance:

- Facilities working in standalone (unconnected or with strong connection restrictions) would have to implement an online event reporting.
- Facilities with connection restrictions would be impacted by several downtime periods, jeopardising the data transmission process.
- Facilities working only with batch processing systems would have to implement an online processing and reporting system.

The definition of the allowed delays for reporting events requires differentiation of the concept of **frequency** from the concept of **delay**:

- **Delay** is the time taken by the economic operator to transmit the event data to the data storage solution since its occurrence, which is the actual subject of this section.

Example: For a one-day allowed delay, if an event occurs at 10:00:00AM, the economic operator shall inform the system before 10:00:00AM of the following day.

- **Frequency** refers to the time at which data is fed at regular intervals. This often refers to whatever time/times (of the day, week, month, year, or any given period) the data feed should happen. Frequency is not the subject of this section.

Accordingly with the TPD, two event data categories must be supported:

- **Traceability data**
- **Trade data**

The process of event reporting must be accomplished within the maximum allowed delay, which includes: the entire process of data capture, any internal data processing needs and/or intermediary steps through the management systems (WMS, MES, ERP, uTrack), and finally the reporting of the event data to the Tracking and Tracing System. Taking that into account, an allowed delay that is too low may directly impact both the economic operator, regarding the necessary time to prepare and compile relevant data prior to reporting; and the Tracking and Tracing System, regarding the necessary time to validate, synchronise and process data prior to becoming effective and ready to be used by the competent authorities.

The structure of the reported data should be based on public standards such as **ISO/IEC 19987** (ISO/IEC 19987:2015 EPCIS, 2016), and shall contain the event occurrence timestamp in a universal *Date Time* format such as UTC. This will allow further temporal event sorting, disregarding the event reporting sequence.

Data exchanged: Connection rates and amount of data exchanged

The total volume of transmitted data will not vary depending on the allowed delay. Instead, the data volume variation will be per connection to report events to the data storage solution. A near real-time system will send a smaller volume of data per connection, while a one-week delay will send a larger volume.

Considering a more demanding production activity scenario, and assuming the report of 1 event per unit packet during the production process (UID generation) plus the following movements (aggregation, dispatch, receipt, re-aggregation, etc.) will produce up to eight event reports per each group of 25,000 unit packets (a pallet). This represents only 0.018% of the total event reporting. The maximum size of an event report message is expected to be around 3KB, including trade data and all technical specs. Assuming such values, it is possible to calculate that a production line speed of 1,000 unit packets per minute working 24x7 can generate, on average, up to 0.1MB of event data to be transmitted per second.

This rate leads to a conclusion that high connection rates are not required. Instead, a standard market wired Internet connection, such as xDSL can support the expected throughput for all the given options (in accordance with the EU average quality of service provided for Internet broadband (European Commision - DG Communications Networks, Content & Technology, 2014)).

Prevention of connection problems:

If a facility experiences any type of connection problem, the existence of a local data buffer, an area shared by hardware devices or program processes that operates at different speeds or with different sets of priorities (Sabitha & Lalitha, 2014, pág. 3), shall retain the event data until the re-establishment of the connection. Then, the feeding process can recover from the buffer the sequence of events that occurred during the eventual downtime. This buffer area is important in order to prevent data loss. To prevent physical or technical connection issues, it is foreseen that the defined system will implement redundant connections to the Internet.

Surveillance and monitoring activities for competent authorities:

For the analysis of the options, all the limitations possibly encountered by the competent authorities during the realisation of audits and inspections have also been considered, since a longer allowed delay would represent a larger number of products within the "blindness" period of the different economic operators. The blindness period refers to a duration of time during which it is not possible to acquire any tracking and tracing information about a recently produced unit packet (period 1 of blindness) or about the movement of the packet (period 2 of blindness). These two blindness periods might represent a weakness in the surveillance process. It has also been reported that EMCS functioning problems make control by competent authorities very difficult.

Despite the allowed delay, it is imperative for the transporter or any other economic operator to report all the events that have occurred and the related data before the movement of products to another facility or any change of custody. Thus, blindness period 2 is avoided, and in case of an inspection, it allows the competent authorities to know the events history, preventing actions that could include a potential product movement stoppage until the arrival of the respective information to the Tracking and Tracing System.

Impact on the local and central system processes and architecture:

Other aspects have also been considered for this analysis, such as the direct impact on data storage areas, the local buffer, and the tracking and tracing data storage, where the longer the allowed delay on reporting an event is, the larger the optional local buffer area will have to be in order to retain data prior to being reported, and the larger the tracking and tracing data storage area will have to be in order to process data and ensure completeness of information.

Within this context, the Inception Impact Assessment defined three alternatives to the allowed delays in reporting events. Choosing the ideal option will depend upon business requirements and technical factors to be evaluated later in this document. The given options have distinct impacts on the solution, which depend upon when or how often the data must be analysed during or after the occurrence of the event.

Option D1: Near real-time reports

Option D2: One-day delay reports

Option D3: One-week delay reports

Each option is explained in the following sections.

1.1.4.1. Near real-time reports

In this option, the economic operator must commit to reporting event messages on a near real-time basis, meaning that a low-latency should exist between the event occurrence and the notification to the data storage solution.

It is significant that near real-time data processing and analytics allow the capability to take immediate decisions when acting within seconds or minutes. That allows the competent authorities to obtain the information required to react prudently at the right time, which almost always means "immediately".

It is important to clarify the difference between a **hard real-time computer system** and a **(soft) near real-time computer system**. The design of a hard real-time system, which must always produce the results at the correct moment, is fundamentally different from the design of a near real-time system. The demanding response time requirements of hard real-time applications, often in the order of milliseconds or less, must be highly autonomous to maintain safe operation of the process.

Taken in the context of this Tracking and Tracing System, the implementation of a hard real-time system would require an event to be reported to the data storage in the exact millisecond of its occurrence. This would thus demand that all of an economic operator's systems and processes be prepared to perform all steps between the event occurrence and the event reporting within a matter of milliseconds. In contrast, a near real-time system can tolerate late answers. The response time requirements are often of several seconds or minutes. That means that the event occurrences will conclude to the total time lag between the actual event occurrence and the elapsed time of the internal data movements necessary to confirm its occurrence. This is due to the existence of some economic operators' internal processes. For instance, an event occurs during a product expedition, this expedition has to be confirmed by the expedition system, which must perform some prior calculations. Then, it is sent to the ERP system to pass through an approval process that confirms the expedition. The latter depends on the conclusion of several other expedition products, and it takes up to one hour to be concluded. In this case, all the processes between the actual time of the event occurrence and its reporting took some time, and the event reporting will only take place after that. In order to avoid the raising of several unreal suspicious movement alerts, a reasonable delay must be allowed to let the natural process occur before being reported to the data storage solution.

This allowed delay option refers to the **near real-time computer system** and requires the definition of this maximum allowed delay. Taking into consideration the criticality of the events and the data processing time, the response time of the systems and reporting should be concluded within 60 minutes (one hour), as a maximum delay. Allowing such a limit on reporting events facilitates the economic operators adapting to the event reporting process.

The near real-time reporting might impose several complications to SMEs, some of which today are still working without any or very limited automation systems and external connectivity. Thus, this scenario poses a high level of complexity for the implementation of this option.

In order to illustrate the concept above and, for a time interval of two weeks (starting from the day of the production of a unit packet up to the moment of its delivery to the first retail outlet), the first event would have happened at moment d1 and been reported up to one hour after moment d1; the dispatch would have happened at moment d13 and

been reported up to one hour after moment d13; and then the final delivery at moment d14. This scenario leads to a maximum interval of about 13 days for the full cycle of event data to be reported to the data storage, with two periods of blindness of less than one hour each, as shown in the image below.

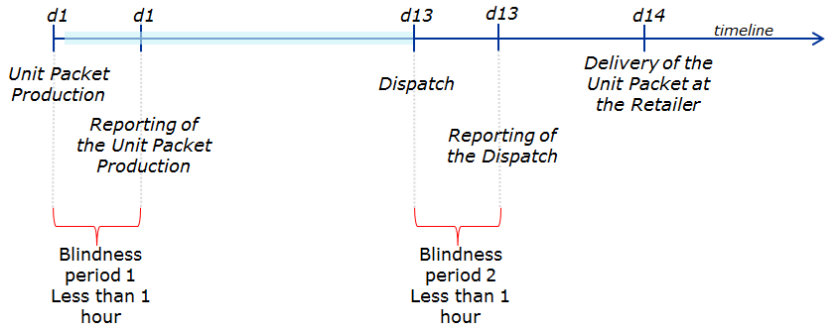


Figure 16: Timeline of the events reporting and blindness periods of near real-time allowed delay

The horizontal blue bar represents the possible occurrence of several other events before the last dispatch event.

A near real-time data reporting delay has the following implications:

- A low-latency business enterprise. The economic operator production line and data transmit channels must be able to access, propagate and process the data in low-latency. That means that any approval or confirmation of the event is done through management software (such as an ERP), and the event reporting must be concluded within this allowed delay.
- A continual input and output of data being processed in a small period of time (near real-time).
- A highly fault-tolerant reporting system on the economic operators' side, with the ability to recover from data report process failure, in order to keep the same level of performance and to deal with any unforeseen problems, such as connection downtimes.
- A small amount of data sent several times, thereby reducing the volume of data to be sent per transmission, which means a very even and balanced volume of data transmission during a given timeframe.
- The possibility for law enforcement to proactively analyse and react upon a potentially risky event reported.

Once the pipeline of data constantly receives analytics in near real-time, as the operations take place, it completes the data feeding cycle and helps to analyse data as the event occurs.

1.1.4.2. One-day delay reports

In this option, the economic operator will have to commit to reporting event messages within a maximum of one day after the occurrence of an event. That means every event will must be delivered to the data storage within 24 hours of its occurrence.

A data feeding with a maximum one-day delay allows the prior data harmonisation and processing to use a larger amount of time. Therefore, decisions are taken disregarding the exact second or minute of the event occurrence, which allows the competent authorities to obtain daily processed and consolidated information.

Considering a time interval of two weeks, starting from the day of the production of the unit packet up to the moment of its delivery to the first retail outlet, the first event would have happened at moment d1 and been reported up to moment d2; the dispatch would have happened at moment d13 and been reported up to moment d14; then the final delivery at moment d14. This scenario leads to a maximum interval of about 13 days for the full cycle of event data to be reported to the data storage, with two periods of blindness of one day each, as shown in the image below.

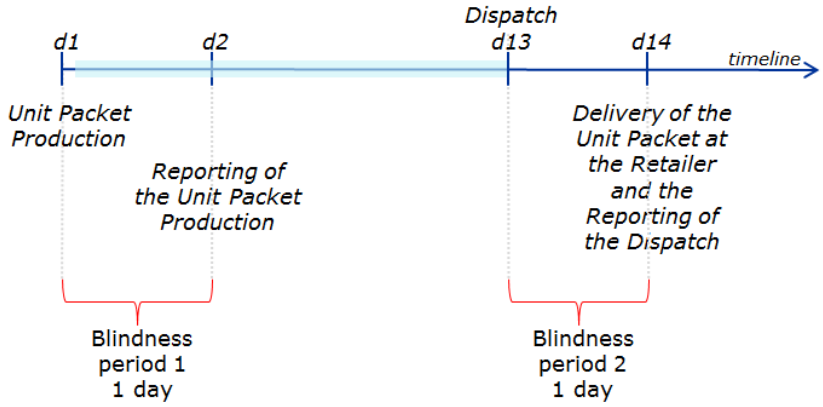


Figure 17: Timeline of the events reporting and blindness periods of one-day allowed delay

Having one-day data reporting delay has the following implications:

- A large time lag tolerance on event reports, which allows the event data to be collected and processed by any internal economic operator's system to approve or confirm the movement (such as an ERP) before being sent to the data storage solution.
- A lower fault-tolerant reporting system, on the manufacturers' and economic operators' side, in order to recover from data report process failure.
- The ability of the systems of manufacturers and economic operators to handle large amounts of data without jeopardising performance, and to process high volumes of data accumulated within a one-day time frame.
- One-day time lag on sending data, which therefore increases the volume of data sent per transmission, when compared with near real-time reporting.
- Risk of sanctions or product transportation halts due to missing information in the Tracking and Tracing System.
- The ability for law enforcement resources to analyse and react upon a potentially risky event reported within just one day.

1.1.4.3. One-week delay reports

In this option, the economic operator will have to commit to reporting event messages within a maximum of one week after the occurrence of an event.

A data feeding with a maximum one-week delay allows for prior data harmonisation and processing within a larger amount of time. Therefore, decisions taken disregard the exact second, minute or even day of the event occurrence, which allows the competent authorities to obtain processed and consolidated information on a weekly basis.

As a matter of clarification, considering a time interval of two weeks (starting from the day of the production of the unit packet up to the moment of its delivery to the first retail outlet), the first event would have happened at moment d1 and been reported up to moment d7; and the final delivery would have happened at moment d14 and been reported up to moment d20. This scenario leads to a maximum interval of nearly 20 days for the full cycle of event data to be reported to the data storage, with two large blindness periods of seven days each, as shown in the image below.

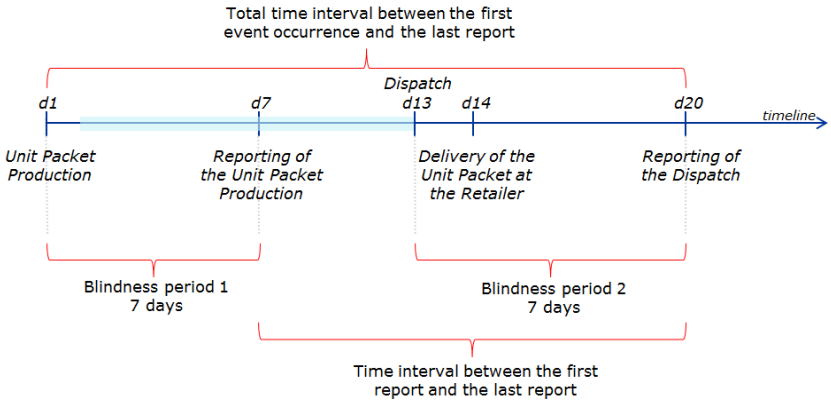


Figure 18: Timeline of the events reporting and blindness periods of one-week allowed delay

Having a one-week maximum data reporting delay has the following implications:

- A very flexible and low fault-tolerant reporting system on the manufacturers' and economic operators' side.
- The ability by the systems of manufacturers and economic operators to handle very large amounts of data collected within one week.
- Sending a large amount of data after one week, which increases the volume of data sent per transmission when compared with one-day delay reporting.
- High risk of sanctions or product transportation halts due to missing information in the Tracking and Tracing System.
- The reporting time lag may lead to absence of information, and therefore seriously obstruct law enforcement actions.

1.1.5. Method of adding a security feature

Article 16 of the TPD (European Commission - TPD Inception Impact Assessment, 2016) states the need to have security features on all unit packets of tobacco products placed on the market, as a medium to fight illicit trade. According to the Directive, all unit packets of tobacco products placed on the market must carry a tamperproof and irremovable security feature, composed of visible and invisible elements.

The TPD also anticipates the possibility whenever possible, to combine what is required in Article 16 of the TPD with the security features currently implemented on the tax stamps or national identification marks used by Member States for tax purposes, provided they fulfil all technical requirements. However, it is important to notice that fiscal marks and security features are different topics, and even in Member States that do not apply any sort of fiscal marks, the requirements for security features set out in Article 16 of the TPD will still apply. To avoid further confusion, it is also important to note that the security features are not linked with the unique identifier or with any data carriers applied to tobacco products.

The definition presented here focuses only on how to add the security features to unit packets of tobacco products. The definition is therefore independent of any specific technologies (e.g. holograms, latent images, etc.) and of the levels of protection applied (i.e. overt, semi-covert, covert and forensic).

The Inception Impact Assessment, in its policy options, defined three methods for adding a security feature:

Option S1: Affixing

Option S2: Printing or integrating through a different method

Option S3: Mixed solution - At least one printed or affixed Security feature

The third option gives the possibility to combine several security elements, and add an additional level of flexibility that can ultimately improve the integrity of the overall system. The figure below demonstrates how different security elements can be combined to generate a fully TPD-compliant security feature.

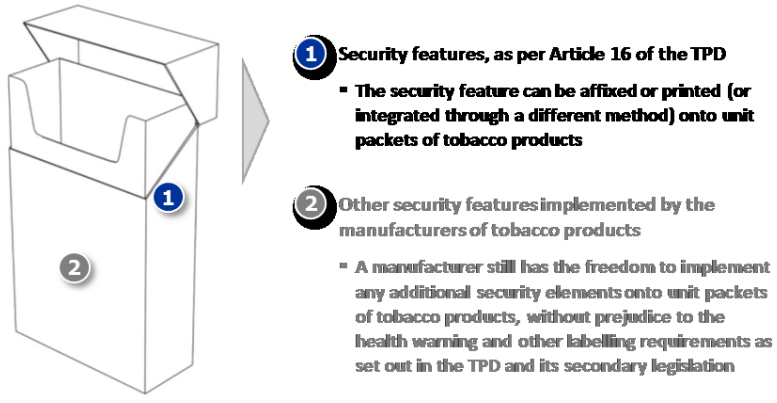


Figure 19: Combination of security elements to generate a full TPD compliant security feature

This combination of security elements can generate a higher level of security so that, for someone to engage in the illicit trade of tobacco products, it would be necessary to circumvent all security elements implemented.

The following sub-sections explain the specific implications of affixing, printing or integrating through a different method, or applying a mixed solution for the implementation of the security feature.

1.1.5.1. Affixing

The first option defined is affixing security features. This is the method of choice for Member States' fiscal marks.

These affixed tax stamps or national identification marks also carry, in most cases, security elements of their own.

Affixed security features are considered to be:

1. Impossible to copy: The TPD foresees the implementation of both visible and invisible security elements, which are by definition impossible to copy. Even if an affixed security feature is photocopied and has the "look and feel" of the real security feature, it should always be discovered upon control.
2. Secured to the product they are applied to, and in accordance with TPD requirements to be tamperproof and irremovable.

Figure 20: Frangible paper

To improve the integrity of this device, the affixed security feature should be placed in an area where the unit packets of tobacco products cannot be opened without breaking the feature.

Also, and whenever possible, the security features should be affixed before the unit packets of tobacco products are wrapped in cellophane. This ensures that the security features are not destroyed during handling and transportation.

When taking into account all points considered above, affixed security features can be applied to all types of tobacco products, regardless of the size and typology of their unit packets.

1.1.5.2. Printing or integrating through a different method

The second option corresponds to the printing or integration of a security feature onto unit packets of tobacco products through a different method.

In principle, this option guarantees higher system integrity, as the security feature is applied directly onto the unit packets of tobacco products. This means the feature cannot be tampered with or removed without destroying the package. Furthermore, given the structure of the packs and the space available to apply them, this option can present various technological options.

Operationally, this option is a better fit for high speed/ high production products – which, in this context, means cigarettes. Cigarettes can be produced at a rate of more than 1000 packs per minute, and represent single-handedly the largest tobacco product market in the EU. This option can also have a reduced impact on the manufacturers' production process, as the security features can be printed or integrated through a different method directly on the production lines, or they can be printed or integrated through a different method at a previous stage (e.g. by their suppliers of packaging material). This option is viable for at least some security elements, provided the security of the production environment, transportation, and storage can be ensured.

For other types of tobacco products, and especially in smaller operations, this option may be harder to implement than an affixed security feature. It may even be impossible to implement in very specific cases: such as cigars that come in wooden boxes, and products like cigarillos and pipe tobacco that can come in metal tins. These are two cases where the physical properties of the product make it very hard to print security features (e.g. holograms) or integrate them through a different method (e.g. micro perforation).

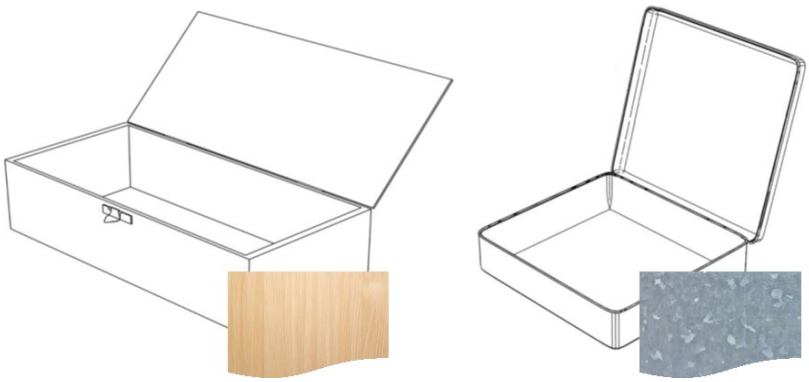


Figure 21: Wooden boxes and metal tins

Given the difficulties presented, a certain degree of flexibility is recommended for tobacco products manufactured in small quantities in order to consider the specifics of each production operation.

1.1.5.3. Mixed Solution

The mixed solution enables the use of **at least one printed or affixed security feature.** This solution will minimise the implementation impact, while complying with all requirements of Article 16(1) of the TPD. Furthermore, in order to comply with Article 16(2) of the TPD about the rotation of security features, affixing is to be understood in

the broader meaning of "attaching in any way" instead of a more restrictive meaning such as "labelling" or "sticking"[10]

The choice of the method of application will depend mainly on the following drivers:

- **The type of tobacco product and packaging**: Printing or integrating security features through a different method is more suitable and more cost efficient for certain types of tobacco products or packaging. For other types of products or packaging, affixing the security features might be a better choice.
- **Member States' preferences**: this solution gives the possibility for Member States to select the most suitable security features taking into consideration the ones already available in their country and used in the associated processes. For instance, Member States using tax stamps as a fiscal marking may decide either to upgrade the security features in these tax stamps in order to comply with the TPD.

Furthermore, regardless of the option chosen, the TPD does not prevent any manufacturer or Member State from implementing additional security elements of their own that they consider necessary for the security of their operations.

[10] The broader definition is provided by the Merriam-Webster legal dictionary: https://www.merriam-webster.com/dictionary/affix#legalDictionary).

1.2. Evaluation of the policy options

The policy options have firstly been evaluated against a set of selection criteria predefined by the Commission. These criteria, and our understanding of them, are presented below. They are split in two groups:

- Primary requirements: Options that do not fulfil these requirements will be discarded in the final selection, even if they score higher than the other options for the secondary requirements.
    - **Full compliance with Articles 15 and 16 of the TPD and Article 8 of the FCTC Protocol**: The option complies with all the requirements established in Articles 15 and 16 of the TPD and Article 8 of the FCTC protocol;
- Secondary requirements: The objective is to select the option that fulfils the selection criteria in the most optimal way.
    - **Technical feasibility**: The option is technically feasible and can be implemented among all economic operators and competent authorities.
    - **Interoperability (with key users' and other companies' systems)**: The option guarantees the interoperability with the systems of key users (both national and European authorities), and with the systems of the economic operators (e.g. to access information that needs to be included in the data carriers).
    - **Ease of operation**: Once it is implemented, the option is easy to operate by the various stakeholders.
    - **System integrity**: The option performs its intended function in an unimpaired manner, free from deliberate or inadvertent manipulation of the system.
    - **System security**: The option ensures or implements proper controls of the accesses to all system resources and data.
    - **Potential of reducing illicit trade**: The degree to which the option contributes to the reduction of illicit trade.
    - **Burden for economic stakeholders**: The administrative/ financial/ economic impact for the economic operators generated by the option has been considered.
    - **Burden for competent authorities**: The administrative/ financial/ economic impact for the European Commission and the competent authorities generated by the option has been considered.

These selection criteria apply to all policy options, which enables a standard comparison and, the selection of the optimal solution. To identify the optimal solution, the selection criteria are assigned different weights and then added up to obtain a final score per option.

1.2.1. Governance model

1.2.1.1. Analysis of the legal compliance of the alternatives for a Governance model

Analysis of the status of the FCTC Protocol

The Protocol to Eliminate Illicit Trade in Tobacco Products was adopted on 12 November 2012. Entry into force of the Protocol requires ratification by 40 Parties (Article 45 of the FCTC Protocol). As of January 2017, 24 Parties, including the European Union, ratified the FCTC Protocol.[11]

The Inception Impact Assessment on Implementing and Delegated Acts under Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU clarified that entry into force of the implementing legislation will make a key contribution to the effective implementation of the FCTC Protocol by the EU.[12]

Analysis of the legal compliance of the alternatives proposed for a Governance model

The legal compliance of the three alternatives proposed for a Governance model (allocating various responsibilities and functions to the operators involved in the supply chain, starting with the manufacturers and providers of necessary services) with the requirements of the FCTC Protocol and the TPD is analysed in this chapter.

Art.	Analysis	Compliance		
		A1	A2	A3
8.2. FCTC Prot.	**Content** Each Party shall establish, in accordance with this Article, a tracking and tracing system, controlled by the Party for all tobacco products that are manufactured in or imported onto its territory taking into account their own national or regional specific needs and available best practice.	Yes	Yes	Yes
	Impact on the Governance model According to this article, the Tracking and Tracing System shall be controlled by the Parties. In order to comply with this requirement it must be ensured that all key governance tasks are placed in the hands of the authorities. Tasks entrusted to the industry must be of a technical nature only. How does this requirement of control impact the Governance model?			

[11] https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4-a&chapter=9&clang=_en (23/01/2016)

[12] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf

Art.	Analysis	Compliance		
		A1	A2	A3
	To **ensure and reinforce this control**, corrective measures shall be implemented in each of the three alternatives (A1, A2 and A3, see below). Control of a Tracking and Tracing System must be considered as the necessary condition (*conditio sine qua non*) to establish a suitable system which enables "Parties to make enquiries and receive relevant information", "[f]or the purposes of further securing the supply chain and to assist in the investigation of illicit trade in tobacco products" (Art. 8(1) FCTC Protocol).			
	Corrective measures The following measures are foreseen in each of the alternatives to ensure the control of the system by the competent authorities: (Alternative A1) Extensive control measures to monitor the process of generation of the serial numbers and to ensure that all the unit packets of tobacco products are marked with a unique identifier. These additional extensive controls include the full time physical presence of enforcement officers on the manufacturers' (and importers') facilities[13] and/or technical solutions (such as anti-tampering devices) that ensure the verification of the marking of all unit packets of tobacco products produced or imported. (Alternative A2) The controls are performed by assigning the tasks of the Governance to an independent third party under the control of the competent authorities. Competent authorities may be required to approve the independent third parties, only after verifying their independence and technical capabilities. (Alternative A3) The control in this alternative is executed through: • The generation of the codes by authorised parties only (independent third party or competent authorities). This generation is independent of the tobacco industry. • Permanent control is implemented for the scanning/verification of the codes by means of anti-tampering devices installed by an independent third party.			
8.3.	**Content**	Yes	Yes	Yes

[13] To ensure effective control, enforcement officers shall monitor the whole process of production (and packaging) of the tobacco products to examine that all the tobacco products are marked with a unique identifier, as required by art. 15.1 of the TPD and 8.3 of the FCTC Protocol.

Art.	Analysis	Compliance		
		A1	A2	A3
FCTC Prot.	With a view to enabling effective tracking and tracing, each Party shall require that unique, secure and non-removable identification markings (hereafter called unique identification markings), such as codes or stamps, are affixed to or form part of all unit packets and packages and any outside packaging of cigarettes within a period of five years and other tobacco products within a period of ten years of entry into force of this Protocol for that Party.			
	Impact on the Governance model The obligation in this article concerns the Parties, who shall require the marking of all unit packets of tobacco products with identification markings within a period of five years of entry into force of this Protocol for cigarettes and within a period of ten years of entry into force of this Protocol for other tobacco products. By implementing the TPD, the EU and its Member States are meeting the requirement of art. 8.3 of the FCTC Protocol.			
	Corrective measures N/A			
8.12. FCTC Prot.	**Content** Obligations assigned to a Party shall not be performed by or delegated to the tobacco industry.	Yes	Yes	Yes
	Impact on the Governance model When analysing the legal compliance of the Governance model, the obligations assigned to a Party in Article 8 of the FCTC Protocol regarding the allocation of various responsibilities and functions to the operators involved in the supply chain are: - To control the Tracking and Tracing System (art. 8.2. FCTC Protocol). - To require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets, packages and any outside packaging of cigarettes (art. 8.3 FCTC Protocol). In the EU, a Tracking and Tracing System is being established by means of art. 15 of the TPD, with technical details to be laid down via Delegated and Implementing Acts. According to Art 8(12) of the FCTC Protocol, the **obligations assigned to a Party** cannot be performed by or delegated to the tobacco industry. Given that the Protocol excludes delegation to the tobacco			

Art.	Analysis	Compliance		
		A1	A2	A3
	industry only, the possibility of delegation to a third party which is independent from the industry remains. Hence, it is reasonable to state that the Governance models complies with Article 8(12) of the FCTC Protocol. In none of the three alternatives proposed for a Governance model are obligations assigned to the Parties performed or delegated to the tobacco industry.			
	Corrective measures N/A			
8.13. FCTC Prot.	**Content** Each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.	Yes	Yes	Yes
	Impact on the Governance model The contacts between the industry and the competent authorities defined in this report are limited to the implementation of the Tracking and Tracing System. In the three alternatives proposed, all the contacts and coordination between the industry and the Parties will be in the context of the implementation and operation of the system.			
	Corrective measures N/A			
15.1 TPD	**Content** Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps or price marks, or by the opening of the unit packet. In the case of tobacco products that are manufactured outside of the Union, the obligations laid down in this Article apply only to those that are destined for, or placed on, the Union market.	Yes	Yes	Yes
	Impact on the Governance model Member States must ensure that all unit packets of tobacco products are marked. This Article does not indicate who should perform this marking. Therefore, in the context			

Art.	Analysis	Compliance		
		A1	A2	A3
	of this article, there are different scenarios which ensure that all tobacco products are marked as required: ○ Member States mark themselves all the unit packets (unrealistic scenario). ○ Member States appoint/pre-approve independent third parties to mark all the unit packets (scenario of alternative A2). ○ Member States delegate the marking to the industry while introducing additional controls to ensure that all unit packets are marked (scenario of alternatives A1 and A3). Depending on the level of controls introduced, this implementation scenario may be capable of meeting the requirements of art. 8.12 of the FCTC Prot., as described in the analysis performed above.			
	Corrective measures The measures to ensure control in the context of art. 8.2 FCTC Protocol also apply.			

1.2.1.2. Detailed evaluation of the alternatives for a Governance model

(A) Governance Model A1: Industry operated solution A2: Third party operated solution A3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**A1**	**A2**	**A3**	**Comments**
T	**Grand total**	**100%**	**N/A**	 **68**	 **83**	 **89**	
A	**Compliance with TPD and FCTC Protocol**						
Please refer to the legal analysis performed above.							
1	**Technical feasibility**	**8,33%**	**100%**	 **100**	 **69**	 **94**	
1-1	Ability to ensure that the unique identifier is applied	2,08%	25%				Sources: • (Directive 2014/40/EU of the European Parliament and of the Council, 2014) • (European Commission - Feasibility

(A) Governance Model A1: Industry operated solution A2: Third party operated solution A3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**A1**	**A2**	**A3**	**Comments**
	(printed/affixed) on time and without major impacts on the production lines						Study, 2015)
		Description: In the process of marking each unit of tobacco product (and different aggregation levels), the unique identifier is integrated in the data carrier together with other relevant information, as stipulated in art. 15.12 of TPD (date and place of manufacturing, facility, machine used, production shift, etc.). In option A1, the industry is in charge of both the generation of the UID and the marking of each unit packet. Therefore, the consolidation of the UID with the additional data required does not represent a challenge. The data carrier (including the UID) shall be applied on time and without major impacts. During the public consultation, some stakeholders expressed that this process takes 'milliseconds' to be completed. On the contrary, in option A2 it is an independent third party who is in charge of the generation of the UID and the marking. But before each marking, this independent third party must receive from the industry all the information required in art. 15.12. Once this information is received, it must be consolidated with the UID and then applied in each unit packet. There is a risk that this process implies (limited) delays in the ability to apply the UIDs into the unit packets. In option A3, this risk is lower: the industry only needs to receive from a third party the code for the UID. Then, it is the industry that is in charge of consolidating the UID with the production information and applying it into each unit packet.						
1-2	Ease of integrating the application equipment on the manufacturers' production lines	2,08%	25%	●	◑	●	Sources: • (Directive 2014/40/EU of the European Parliament and of the Council, 2014) • (Ross, 2015)
		Description: An optimal solution will keep the administrative and technical measures as simple as possible, with limited intrusion and capable of practical adoption even in smaller business (Ross, 2015, p. 4) . In this sense, options A1 and A3 score the maximum in this criterion. In option A1, because all the functions are performed by the own industry itself, limiting the impact of an external actor involved in the process. However, the intensive control measures required under this option need to be considered. In option A3, even if it is a mixed solution, the involvement of an independent third party is limited to the generation of the codes for the UIDs. This generation would normally be done in a central server located outside the premises of the manufacturers. Therefore, option A3 would also limit the operational impact. On the contrary, option A2 foresees the installation and operation of equipment of an independent third party in the producing facilities, in order to mark and scan all the codes, bringing an evident operational impact on the manufacturing process.						
1-3	Ability to adapt to all tobacco products	2,08%	25%	●	●	●	Sources: • (Directive 2014/40/EU of the European Parliament and of the Council, 2014) • (European Commision - Targeted stakeholder consultation TPD, 2015) • (Ross, 2015)
		Description: The TPD requires (art. 15.13) that all unit packets of cigarettes and RYO tobacco are marked from 20 May 2019, and that tobacco products other than cigarettes and RYO tobacco are marked from 20 May 2024. Therefore, the system must be able to mark all different types of tobacco products. In options A1 and A3, the industry is responsible for marking their own production. In the market, there is equipment available able to adapt to all types of tobacco products. Depending on the production of tobacco, each manufacturer/importer should adapt their production lines accordingly. In the case of option A2, where the marking of the tobacco products is allocated to						

<table>
<tr><th colspan="8">(A) Governance Model
A1: Industry operated solution
A2: Third party operated solution
A3: Mixed solution</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>A1</th><th>A2</th><th>A3</th><th>Comments</th></tr>
<tr><td></td><td></td><td colspan="6">independent third parties, the criteria is not a challenge either. During the targeted stakeholders' consultation, multiple independent third parties expressed their willingness to get involved in the system and declared their capabilities to adapt to all types of tobacco products. When concluding contracts with them, manufacturers and importers shall select the independent third party that suits better with their type of tobacco product manufactured or imported. A list of companies offering these services may also be found in (Ross, 2015, p. 9).</td></tr>
<tr><td rowspan="2">1-4</td><td rowspan="2">Ability to apply the UID on all aggregation packaging levels</td><td>2,08%</td><td>25%</td><td>  </td><td>  </td><td>  </td><td>Sources:
• (Directive 2014/40/EU of the European Parliament and of the Council, 2014)
• (Ross, 2015)</td></tr>
<tr><td colspan="6">Description:
In order to effectively track and trace products, the Tracking and Tracing System must allow for aggregation (i.e. linking of a pallet to a mastercase to a carton and to a unit packet (Ross, 2015, p. 7)) (Art. 15(5) TPD). The Tracking and Tracing System must also be able to allow the marking of all the potential disaggregation and re-aggregation. This process may affect not only the manufacturers and importers, but also the distributors of tobacco products. As in the process of marking each unit packet, the aggregation packaging levels must be marked not only with the UID but also with other information regarding the production. For both options A1 and A3, it is foreseen that the manufacturers, importers and distributors (when needed) generate the UIDs for the aggregation packaging levels. They are also in charge of consolidate these UIDs with other required information and mark the aggregation packaging levels. Therefore, the ability to mark each aggregation level is not a challenge in these two alternatives.
Regarding option A2, the marking of each aggregation level falls into the responsibility of an independent third party. Fluent coordination and communication between the independent third party and the economic operators is crucial, in order to be able to mark effectively all the aggregation levels.</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Interoperability</td><td rowspan="2">8,33%</td><td rowspan="2">100%</td><td>  </td><td>  </td><td>  </td><td rowspan="2"></td></tr>
<tr><td>50</td><td>100</td><td>75</td></tr>
<tr><td rowspan="2">2-1</td><td rowspan="2">Ensure that the Tracking and Tracing System is interoperable with any other supply chain equipment</td><td>8,33%</td><td>100%</td><td>  </td><td>  </td><td>  </td><td>Sources:
• (Ross, 2015)
• (European Commission - Feasibility Study, 2015)
• (KPMG and GS1, 2014)</td></tr>
<tr><td colspan="6">Description:
Several sources point to the importance of the use of open standards to contribute to the global effectiveness of a Tracking and Tracing System. In this line, experts state that the proprietary nature of the systems developed by the industry challenge the whole interoperability of the system (Ross, 2015, p. 21), and KPMG affirms that "the best way to achieve this on a global scale is through using open standards rather than proprietary solutions" (KPMG and GS1, 2014, p. 35).
The whole configuration of option A1 is based on the systems developed and operated by the industry itself. The interoperability of these solutions with the systems of other companies involved in the supply chain of tobacco products is at stake. On the contrary, in option A2 (operated by independent third parties), the interoperability is enhanced as they shall work based on technical standards. Option A3 would be in an intermediate position, as the generation of the UIDs is meant to be done by an independent third party and/or the competent authorities, while the industry would be in charge of marking each unit of tobacco products and scanning and verifying the codes.</td></tr>
<tr><td>3</td><td>Ease of operation</td><td>8,33%</td><td>100%</td><td>  </td><td>  </td><td>  </td><td></td></tr>
</table>

<table>
<tr><th colspan="7">(A) Governance Model
A1: Industry operated solution
A2: Third party operated solution
A3: Mixed solution</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>A1</th><th>A2</th><th>A3</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td></td><td>100</td><td>50</td><td>100</td><td></td></tr>
<tr><td rowspan="2">3-1</td><td rowspan="2">Impact on the operational processes of the manufacturers</td><td>8,33%</td><td>100%</td><td>  </td><td>  </td><td>  </td><td>Sources:
• (European Commission - Feasibility Study, 2015)</td></tr>
<tr><td colspan="6">Description:
The general aim of the governance model is to fulfil the objectives of the system, ensuring full control of the traceability while limiting the negative impact on the operations of the economic stakeholders involved in the supply chain. The configurations detailed in options A1 and A3 score the maximum in the criteria of ease of operation of the system. In both alternatives, the industry is in charge of some of the operational technical processes (printing or affixing and scanning/verifying the codes). Therefore, these two alternatives score higher in ease of operation compared with option A2. However, the intensive control measures required, in particular as regards option A1, need to be taken into consideration. In the option operated by an independent third party, however, the ease of operation of the system is affected, as it requires the presence of personnel of the independent third parties in the facilities of the manufacturers to install, operate and maintain their equipment.</td></tr>
<tr><td>4</td><td>System integrity</td><td>12,50%</td><td>100%</td><td>  </td><td>  </td><td>  </td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>50</td><td>92</td><td>83</td><td></td></tr>
<tr><td rowspan="2">4-1</td><td rowspan="2">Ensure the integrity of the system when multiple parties are involved</td><td>4,17%</td><td>33,33%</td><td>  </td><td>  </td><td>  </td><td>Sources:
• (European Commission - Feasibility Study, 2015)</td></tr>
<tr><td colspan="6">Description:
The integrity of the system is not challenged when the entire system is managed by a single actor, as is the case in option A1. All the processes of the system are allocated to the industry, reducing the risk of integrity breaches due to non-coordination between actors involved in the system with different responsibilities. At the same time, the intense control by competent authorities and/or third parties required for this solution needs to be taken into account.
In alternatives A2 and A3, a smooth cooperation between the industry and third parties is needed to ensure the robustness of the system and its potential to reduce illicit trade. There are limited risks for the integrity of the system in these two options.</td></tr>
<tr><td rowspan="2">4-2</td><td rowspan="2">Ensure that the independence of the system from the industry is maintained in the medium/long term</td><td>4,17%</td><td>33,33%</td><td>  </td><td>  </td><td>  </td><td>Sources:
• (European Commission - Feasibility Study, 2015)</td></tr>
<tr><td colspan="6">Description:
Option A2 presents the highest level of independence from the industry, as the entire system is operated by independent third parties. The independence of these three parties in the medium and long term is ensured by:
• An initial assessment by the authorities of the independence and technical capabilities of the third parties proposed by the industry to perform the activities.
• A periodic re-assessment of this independence. If a lack of independence is identified, this approval may be withdrawn.
In option A3, even if some of the operational processes are allocated to the industry for the sake of technical feasibility and to minimise the impact on the production lines, the involvement of a third party in the generation of the UIDs contributes to maintain the independence of the system in the medium and long term. The same framework of approvals and regular checks of independence apply.
On the contrary, to maintain an acceptable level of independence of the system from the industry in option 1, where key activities of operating the system are managed by the industry, a substantial effort needs to be done – and maintained – by the</td></tr>
</table>

(A) Governance Model A1: Industry operated solution A2: Third party operated solution A3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**A1**	**A2**	**A3**	**Comments**
		competent authorities.					
4-3	Provide additional levels of independence and transparency to the Tracking and Tracing System	4,17%	33,33%				Sources: • (European Commission - Feasibility Study, 2015) • (Ross, 2015)
		Description: Industry operation solutions are so far based on self-regulation and trust (Ross, 2015, p. 14). In order to comply with the legal requirements of control and independency, a series of intensive controls need to be put in place, so that Member States can ensure that all unit packets of tobacco products are marked. But option A1, *per se*, does not provide additional levels of independency and transparency to the Tracking and Tracing System. In option A2, the system is operated entirely by an independent third party, whose independency and capabilities are assessed by the authorities. This approval does not only take place at an initial stage, but should be renewed periodically to ensure that this independence is maintained in the medium and long run. The activities of these independent third parties should also be monitored by an external auditor, adding two additional levels of independency to the system. In option A3, the fact that the UIDs are generated by an independent third party or by the competent authority itself allows a reconciliation between the codes generated and the units marked at the level of the data storage. This reconciliation, combined with recurrent and frequent audits, as well as possible additional control measures, also provides additional levels of independency and transparency of the Tracking and Tracing System.						
5	**System security**	**12,50%**	**100%**	 **75**	 **75**	 **75**	
5-1	Guarantee of a secure environment for the generation of unique identifiers	12,50%	100%				Sources: • (European Commission - Feasibility Study, 2015)
		Description: There are always risks on the generation of the unique identifiers, whether this is performed by the industry or by a third party (manipulation, generation of undesired/unauthorised codes or access by unauthorised parties to the central server, amongst others). But these risks are the same across the three options. However, there are several controls that can be implemented and that may be relevant, such as: • Generation should take place in a secure, controlled environment with appropriate security measures in place to protect the central server, and only authorised parties should be allowed to request for codes. • Across all the options, audits performed by external auditors and by the competent authorities are foreseen; to increase the security of the generation of the UIDs. • The algorithms behind the generation of the codes should be protected from unauthorised parties.						
6	**Potential of reducing illicit trade**	**25,00%**	**100%**	 **75**	 **100**	 **100**	
6-1	Potential of reducing illicit	25,00%	100%				Sources: • (European Commision - Targeted stakeholder consultation TPD, 2015) • (European Commission - Public

(A) Governance Model A1: Industry operated solution A2: Third party operated solution A3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**A1**	**A2**	**A3**	**Comments**
	trade						consultation TPD, 2016)
		Description: Reducing illicit trade is the main goal of the implementation of the Tracking and Tracing System. This is also one of the core objectives of the TPD. None of the three options has any contradiction with the obligations set in the Directive, as explained in the legal analysis performed. They are aligned with the aim of the system and may be regarded as reasonable governance models to achieve the objectives of the TPD. However, option A1 presents breaches in its potential to reduce illicit trade: current track and trace solutions implemented (and operated) by the industry have proven themselves ineffective to fight against illicit trade. Even if the option A1 shall not be confused with current T&T solutions developed by the industry (the control is enhanced, technical requirements are being defined), we shall not evaluate option A1 equally with options A2 and A3 in its potential to reduce illicit trade. In this sense, it is valuable to highlight the Preamble of the FCTC, which explains that the Parties "need to be alert to any efforts by the tobacco industry to undermine or subvert strategies to combat illicit trade in tobacco products and the need to be informed of activities of the tobacco industry that have a negative impact on strategies to combat illicit trade in tobacco products".						
7	**Administrative / financial burden for economic stakeholders**	**12,50%**	**100%**	 **100**	 **50**	 **75**	
7-1	Burden for economic stakeholders	12,50%	100%				Sources: • Cost Analysis • (European Commission - Feasibility Study, 2015) • (European Commission - Impact Assessment FMD, 2008)
		Description: When analysing the burden for economic operators, Option A1 gets the highest score as it implies the lowest costs for the economic operators. All the processes for generation of the UID, marking the unit packets (and aggregation levels) and scanning and verifying the codes are done by the industry themselves. Option A2, on the contrary, implies higher costs for the economic operators. The processes of generation UID, marking the tobacco products and scanning/verifying the codes are delegated to a third party. These third parties, even if they can beneficiate of their know-how and economies of scale, seek to obtain a commercial profit out of these services, so the cost of the while process is higher for the economic operators (compered if they would perform these activities themselves). On top of that, an external auditor shall be contracted to monitor the activities of the independent third parties. Option A3 follows the same reasoning than in case of A2. Some of the activities are delegated to an independent third party, resulting in an increase of the cost. However, the impact of this increase is limited, and only applicable to those activities allocated to the third party (and not to the whole process). More details may be found in the cost analysis for the governance model.						
8	**Administrative / financial burden for competent authorities**	**12,50%**	**100%**	 **0**	 **100**	 **100**	
8-1	Burden for competent authorities	12,50%	100%				Sources: • Cost Analysis • (Eurostat, 2013) • (European Commission - Feasibility Study, 2015)

(A) Governance Model A1: Industry operated solution A2: Third party operated solution A3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**A1**	**A2**	**A3**	**Comments**
		Description: When analysing the burden for competent authorities, there is an important difference between option A1 (industry operated solution) and the other two options. As discussed when analysing the legal compliance of the three options, we have concluded that the TPD requires Member States to ensure that all unit packets of tobacco products are marked with a unique identifier. Therefore, in option A1 the competent authorities must put in place intensive controls over the whole system, to meet the requirements of the TPD. These intensive controls are translated into higher costs. For options A2 and A3, the financial burden for the competent authorities presents minor differences. More details may be found in the cost analysis for the governance model.					

Table 4: Governance model – detailed evaluation of the policy options

1.2.2. Data storage models

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
T	**Grand Total**	**100%**	**N/A**					
				91	**53**	**45**	**79**	
A	**Full compliance with TPD and FCTC Protocol**	**0,00%**						
				0	**100**	**100**	**100**	
B1 is considered not to be compliant with the primary requirements because the A-8 criterion of this category is not fully accomplished.								
A-1	Ability to store the entry, intermediate movements and the final exit of the unit packets of tobacco products	0,00%	12,5%					Sources: • (ISO/IEC 19987:2015 EPCIS, 2016) • (GS1 System Architecture, 2016) • (WHO - FCTC, 2010) • (Rx-360 Consortium, 2014) • (KPMG and GS1, 2014) • (Booz | Hallen | Hamilton, 2014) • (European Commision - Targeted stakeholder consultation TPD, 2015)

<table>
<tr><th colspan="9">(B) Data Storage Models
B1: Centralised storage
B2: Decentralised storage per manufacturer/importer
B3: Decentralised storage per Member State
B4: Combined storage: centralised for surveillance and decentralised for recording</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>B1</th><th>B2</th><th>B3</th><th>B4</th><th>Comments</th></tr>
<tr><td></td><td></td><td colspan="7">Description:
The optimal solution shall be based on open standards, to the maximum extent possible, if available and applicable.

GS1 is the world-wide reference non-profit organisation dedicated to the design and implementation of global standards to improve the efficiency and visibility of supply chain globally and across sectors.

In this regard, the GS1 System Architecture is a collection of standards and guidelines, which support the business processes information needs through the supply chain, and are grouped into the following conceptual layers: a) Identify, which includes standards to refer unambiguously to a real world entity; b) Capture, which includes standards to automatically capture data that is carried on physical objects; and c) Share, which include standards for exchange information between trading partners or internally with other enterprise applications.

Concerning the A-1 criterion, the evaluation focuses on the standards comprised in the GS1 System Architecture Share layer. The most relevant for the TPD purposes is the ISO/IEC 19987:2015 EPC Information services. This standard specifies how to share the different events that may happen in the supply chain (e.g. dispatch, reception, goods movement, trade, and (dis-)aggregate). This includes the data model along with the technical communication protocols to securely exchange this information.

Once the exchange has been accomplished, data has to be stored. On this point, the GS1 Share layer is agnostic of the underlying storage architecture and allows for establishing different models and using any database technology. Nonetheless, the GS1 System Architecture envisages different storage topologies, which fit with the options proposed within the study (e.g. centralised (B1), federated with routing services (B2 and B3) and federated with replication (B4)). These storage topologies assume that data is exchanged through some Share standard.

Finally, it should be noted that some studies, namely (Rx-360 Consortium, 2014), (KPMG and GS1, 2014) and (WHO - FCTC, 2010), recommend the usage of ISO/IEC 19987:2015 EPC Information services (formerly named GS1 EPCIS) on the basis of its completeness, flexibility and proved functioning in international supply chain production systems. Also, some stakeholder consultations within the pharma and tobacco supply chain showed wide support for this standard.

Therefore, if the options assume the usage of this standard, or another with the same features, this criterion could be considered fully accomplished by all the options.</td></tr>
<tr><td rowspan="2">A-2</td><td rowspan="2">Ability to store information about any transaction of tobacco products</td><td>0,00%</td><td>12,5%</td><td></td><td></td><td></td><td></td><td>Sources:
• Same as criterion A-1</td></tr>
<tr><td colspan="7">Description:
The standard introduced in criterion A-1 also specifies how to exchange trade information to be stored later. As such, criterion A-2 could be considered fully accomplished by all the options if the options are based on this standard, or another with the same features.</td></tr>
<tr><td rowspan="2">A-3</td><td rowspan="2">Guarantee that an external auditor shall be able to monitor the activities of the Data Storage Service Provider</td><td>0,00%</td><td>12,5%</td><td></td><td></td><td></td><td></td><td>Sources:
• (O'Reilly, 2016)
• (Amazon, 2017)
• (Google, s.f.)
• (Microsoft, 2017)</td></tr>
<tr><td colspan="7">Description:
Prior to the definition of the options, the mandatory requirements from the TPD and the Protocol have been identified. These requirements include, amongst others, that the third party data storage provider activities shall be monitored by an external auditor. This is a mandatory requirement that shall be fulfilled by all the options in order to guarantee this legal and mandatory requirement.</td></tr>
</table>

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		The procedures and mechanism for such monitoring shall still be defined, but the monitoring is a common practice provided by many hosting providers. As such, this criterion is considered fully accomplished by all the options.						
A-4	Guarantee that economic operators shall not be able to modify or delete data hosted in the data storage solution	0,00%	12,5%	●	●	●	●	Sources: • Same as criterion A-1
		Description: In addition to the standardisation information introduced in criterion A-1, since any option shall be based on open standards, these data exchange standards shall also support the possibility of authentication and authorisation features to guarantee that economic operators are not able to modify or delete data from the repository. As such, this criterion could be considered fully accomplished by all the options, if the options are based on open standards that support security mechanisms.						
A-5	Guarantee that the Commission, competent authorities of the Member States shall have full access to the data storage solution	0,00%	12,5%	●	●	●	●	Sources: • Same as criterion A-1
		Description: The envisaged authentication and authorisation capabilities shall allow guaranteeing that competent authorities, the Commission and the external auditor have full access. As such, this criterion could be considered fully accomplished by all the options.						
A-6	Guarantee that personal data shall only be processed in accordance with the rules and safeguards laid down in Directive 95/46/EC	0,00%	12,5%	●	●	●	●	Sources: • (European Commission - TRACES, 2016)
		Description: All the options guarantee the mechanism to process personal data in accordance with the rules and safeguards laid down in Directive 95/46/EC through the Cross Cutting Services layer included in all the options. The procedures and mechanism for implementing such personal data processing guarantee shall still to be defined, but this is a common requirement that has been already implemented in European projects. As such, this criterion is considered accomplished by all the options.						
A-7	Guarantee that the obligations assigned to the competent authorities are not performed or delegated to the tobacco industry	0,00%	12,5%	●	●	●	●	Sources: • Same as criterion A-4
		Description: As referred in criterion A-4, since all the options allow the establishment of access control to the data storage solution, through the security policies that have to be defined within the Tracking and Tracing System, it can be guaranteed that the tobacco industry will not have credentials with sufficient permissions to execute unauthorised actions (e.g. access to the Consumer Interfaces, which actually will be granted to the competent authorities and the Commission).						
A-8	Guarantee the legal compatibility with the TPD provisions	0,00%	12,5%	○	●	●	●	Sources: • (Directive 2014/40/EU of the European Parliament and of the Council, 2014) • (Dunne, 2016)
		Description: Option B1 implies that all manufacturers and importers would enter into contractual agreement with a single data storage provider. However, the TPD is not entirely conclusive regarding the possibility for the Commission to impose a single provider to manufacturers and importers. On one hand, Recital (31) states that "manufacturers of tobacco products should conclude data storage contracts with independent third parties", using the plural to refer to the data storage providers. On the other hand, Article 15(8),						

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		paragraph 1, states that "manufacturers and importers of tobacco products conclude data storage contracts with an independent third party", with third party being this time in the singular. Therefore, having said the above, B1 fails in the scoring of this criterion. On the other hand, this criterion is considered fully accomplished by the other options (i.e. B2, B3 and B4) because these options allow for the possibility of having several data storage providers. Hence, since options B2, B3 and B4 do not impose a single provider to manufacturers and importers, this Study considers that are fully compatible with the TPD provisions related to the data storage provider.						
1	**Technical feasibility**	**20,00%**						
				87,50	**50,00**	**43,75**	**68,75**	
1-1	Degree of efficiency of read accesses	10,00%	25,00%					Sources: • (Tanenbaum & Steen, 2006) • (European Commision - Targeted stakeholder consultation TPD, 2015) • (O'Reilly, 2016) • (Tate & al., 2016) • • (Kang, Park, & Youm, 2016) • (Amazon web services, 2016)
		Description: According to the literature, Options B2 and B3 belong to the decentralised architecture type. These options are characterised by a logical partitioning of components in different distributed systems (i.e. data storage solutions) where each distributed system features specific functionalities (i.e. storage of data based on who has manufactured/imported that data – B2, or where is manufactured/imported that data). As such, every data storage solution processes and stores its own data as a distributed and autonomous system. But, in order to facilitate the surveillance activities that should be conducted by the competent authorities, a central solution is needed (i.e. Federation Services solution) in order to give the appearance of a single coherent system. The Federation Services solution is aware of all the distributed systems and seamlessly communicates to them to retrieve data as per surveillance purposes. However, this central Federation Services solution poses two main drawbacks when analysing accesses for reading purposes: a) adds additional complexity to the overall solution (in comparison with the centralised) because it means the need of additional components (e.g. Discovery Service, etc.) that would introduce additional delays, other potential points of failure, more development and maintenance costs, etc.; b) introduces a penalty on the reading performance because in order to realise a surveillance request from the competent authorities, the Federation Services solution has to forward that query to each of the data storage solutions, wait for the individual results and merge the collected data. This penalty on the reading performance could increase with the increase of volume of data handled by the repositories. Thus, this search process will be surely slower than searching against a local database index engine, such as can be done with options B1 and B4; c) there could be potential cross-storage compatibility problems because each data storage implementation could interpret the specifications differently; and c) accessibility to data may be affected negatively if some of the individual data storage solutions do not perform properly or are not available. These drawbacks in the decentralised architecture options point to a lower scoring of B2 and B3 with respect B1 and B4. Although B4 comprises decentralised data storage solutions, there are not used for reading, only for writing. This is the reason why the drawbacks of the distributed data storages solutions have not been considered on the						

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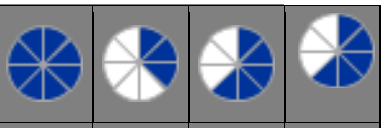
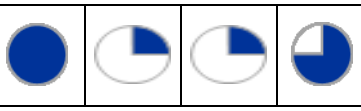
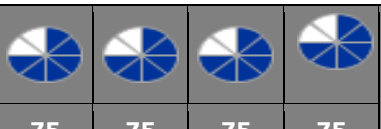
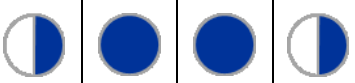
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		read accesses. Finally, it should be noted that irrespective of the option, the Tracking and Tracing System has a data sizing challenge. Therefore, it is highly recommended to embrace data storage best practices for large scale systems such as establishing separate physical data storage areas according to the project needs and priorities such as frequency of access (e.g. the more often accessed should be stored in the quicker storage tier), age of data, protection or specific business rules. Thus, such tiered storage approach can deliver the required combinations of performance, capacity and resilience. As a minimum, two tiers of data are recommended according to current state of play: a "hot" tier with short response times and a "cold" tier with longer response times. When required, data could be moved between tiers automatically.						
1-2	Degree of efficiency of write accesses	10,00%	25,00%					Sources: • Same as criterion 1-1
		Description: Following the basis of the rationale introduced above at 1-1 criterion, for writing purposes the Federation Services solution is also needed in options B2 and B3 because of the decentralised architecture. This central solution comprises the Repository Router component, which is aware of all the distributed systems and can seamlessly communicate to them to record data as per reporting purposes. In this particular criterion, option B4 and its Repository Router, is considered along with the other "pure" distributed options since the B4 writing approach is distributed as well. However, as with criterion 1-1, this central component (i.e. Repository Router of B2, B3 and B4) poses two main drawbacks when analysing accesses for writing purposes: a) adds additional complexity to the overall solution (in comparison with the centralised B1); and b) introduces a penalty on the writing performance from the point of view of the clients (i.e. distributors and wholesalers). This is because the writing process is done through the Repository Router, which actually routes data between the distributed repositories. It should be noted that option B1 will need to process a high volume of data, not only for writing but also for reading. As such, if the storage is not designed properly, the writing operations may influence the performance of the reading requests if both accesses are done to the same physical system. This impact on performance for option B1 could be mitigated with the combination of several strategies such as the following: a) tiered storage (e.g. establishing two separate physical data systems for reading and writing, and a synchronisation process between them; b) establish a sharding strategy taking into account the most critical accesses; c) establishing a throttling controller to regulate the inbound and outbound communication rates; or d) establish a high throughput message broker to deal with a high volume of concurrent requests. The final design and implementation techniques of the storage solution will be decided by the third party data storage provider in order to achieve the required performance. Thus, although the writing access of B1 may have an impact on the performance because of the storage size, it is considered to be less than the writing impact of B2, B3 and B4 because in these particular cases data is routed through an additional component. Therefore, option B1 achieves the highest scoring because it is the most effective (i.e. less complexity and better performance when writing). Option B3 scores the lowest because, in addition to the aforementioned solution complexity: a) the importers that have not established a data storage solution would need to use the Repository Router; and b) the logic to be applied for routing the reports as per Member State could be more complicated (e.g. each Member State may have its own rule to be applied) than as per manufacturer/importer. Options B2 and B4 score in between because in this particular case only distributors and wholesalers use the Repository Router.						

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
1-3	Availability of up-to-date technology that supports the solution	10,00%	25,00%					Sources: • (Axway, 2011) • (IBM and Matiq, 2008) • (FOSSTRAK, 2010) • (European Commission - TRACES, 2016) • (European Commission - DG HOME, 2016) • (GS1 System Architecture, 2016) • (INSPIRE, 2011)
		Description: Option B1 scores the highest because a) based on the rationale of 1-1, with a solution based on specific supply chain standards, there are currently available not only standards related to store and share supply chain data but also some commercial and open-source solutions; and b) there currently exist European systems with central repositories. With regards the Discovery Service needed in options B2 and B3, according to GS1 System Architecture document, there is not yet a GS1 standard nor GS1 services for Data Discovery. Although, a standardisation initiative was on-going, the GS1 Global Standards Management Process Discovery Services project, no standardisation outcome was concluded because the users' needs at that time were more focused on more elementary issues, such as capturing and sharing EPCIS events with direct trading partners. Thus, it is not envisaged that in the short term an open standard could close this gap. Therefore, options B2 and B3 score the lowest because they mostly need a Discovery Service component for reading accesses and there are no available up-to-date technology nor open standards that deal with this topic. Finally, it should be mentioned that in other domains, there are available standards related to the discovery service capability, such as the European INSPIRE Discovery Service to exchange geospatial metadata between repositories, but the data model exchanged is exclusive to that domain. Option B4 also scores low because there are no real references available of supply chain projects establishing such specific synchronisation mechanisms.							
1-4	Guarantee the availability of the data storage solution as a whole	10,00%	25,00%					Sources: • (Tanenbaum & Steen, 2006) • (O'Reilly, 2016)
		Description: Option B1 has the lowest scoring because it is a central solution and the risk of unavailability is higher than with models comprising distributed systems (i.e. B2, B3, and B4). B2, B3 and B4 do not score the maximum because a certain level of unavailability is always possible.						
2	**Interoperability (with key users' and other company's systems)**	**10,00%**						
				93,75	**93,75**	**93,75**	**93,75**	
2-1	Ensure that the recording of traceability and trade data interoperates with the systems of manufacturers and importers	2,50%	25,00%					Sources: • Same as criterion A-1 • (European Commission - Feasibility Study, 2015)
		Description: As elaborated in criterion A-1, since any option shall be based on open standards, none of the options would cause specific interoperability issues to communicate with the						

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		systems of the manufacturers and importers. Thus, all the options score the highest. Also, it should be noted that many of the manufacturers consulted during the Feasibility Study, reported the fact that were already using GS1 EPCIS standards to exchange supply chain data with other companies.						
2-2	Ensure that the recording of traceability and trade data interoperates with the systems of distributors and wholesalers	2,50%	25,00%					Sources: • Same as criterion A-1 • (European Commission - Feasibility Study, 2015)
		Description: As with criterion 2-1, none of the options should cause specific interoperability issues to communicate with the systems of the distributors and wholesalers if based on standards, as they shall be. However, in this particular criterion, it should be remarked that during the Feasibility Study, an association of industry distributors and wholesalers indicated that less than approximately 60% of these economic operators are using electronic systems for recording the receipt and dispatch of consignments. Thus, this would mean a significant impact because of their current IT maturity level is not high. As such, the Study considers that the time needed to establish a smooth integration with the new Tracking and Tracing System might be bigger, as an average, for distributors/wholesalers than for manufacturers/importers. For this reason, all the options score equally, but none score perfectly.							
2-3	Interoperability with the Excise Movement and Control System (EMCS)	2,50%	25,00%					Sources: • (EMCS SEED, 2016) • Same as criterion A-1
		Description: EMCS allows interface with the customs systems of the competent authorities. Since all the options proposed include a Consumer Interfaces layer, which will support any additional extension, based on open standards as elaborated in criterion A-1, the requirement of interoperability with the EMCS system shall be fully accomplished by realising that EMCS interface. For this reason, all the options score perfectly.						
2-4	Interoperability with the System for Exchange of Excise Date (SEED)	2,50%	25,00%					Sources: • (EMCS SEED, 2016) • (OASIS SOAP, 2007) • Same as criterion A-1
		Description: The SEED maintains a list of all authorised economic operators at an EU level in a central repository maintained by the Common Domain central services. This data currently is made available to the competent authorities to complete administrative verifications using a SOAP channel should poll the SEED system for updates. Since all the options proposed include a Consumer Interfaces layer, which will support any additional extension, based on open standards such as SOAP, as was elaborated in criterion A-1, the requirement of interoperability with the SEED system shall fully accomplished realising that SEED interface. For this reason, all the options achieve the highest score.						
3	**Ease of operation**	**10,00%**						
				100	**75,00**	**50,00**	**75,00**	
3-1	Impact on the operational	3,33%	33,33%					Sources: • Same as criterion A-1

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
	processes of the manufacturers and importers	Description: The impact on the operational processes of the manufacturers and importers is due to the fact that they would be required to report certain events within a specific allowed delay. Such reporting implies a remote request to the data storage solution. As such, the availability of the data storage solution and its response time is what potentially could have a major impact on the operational processes. If there is no possibility of reporting or each reporting lasts too long, there will impact on the operational processes. All the options provide a direct interface to the manufacturers and importers. Also all the options shall perform effectively on writing accesses with respect the manufacturers. Thus, B1, B2 and B4 score the highest. Option B3 scores a bit lower, because the importers which have not established a data storage solution, would need to use the Repository Router service since the repositories are distributed per Member State. As such, an additional delay is introduced in the response because it could mean two remote requests if the target repository is not the accessed one at first. This criterion assumes that the data storage solution publishes standard and open interfaces, as elaborated in criterion A-1.							
3-2	Impact on the operational processes of the distributors and wholesalers	3,33%	33,33%					Sources: • Same as criterion A-1 • Same as criterion 1-2
		Description: As with criterion 3-1, the impact on the operational processes of the distributors and wholesalers, is also based on the response time effects depending on the option. Thus, as it was analysed in criterion 1-2, the fact of connecting to the Repository Router implies an additional penalty on performance when writing (options B2, B3, B4). The Study assigns a lower scoring to B3 because more stakeholders would need to use the Repository Router within this option (i.e. importers that do not establish their own data storage solution). Option B1 scores the highest because the reports are sent directly to the data storage solution. In the case of disruption of service of the Federation Services solution, options B2 and B3 indeed allow that distributors and wholesalers were able to upload information directly in the data storage solution, as an alternative transmission mechanism.							
3-3	Ease to operate and maintain all the sub-systems involved to implement the whole data storage solution	3,33%	33,33%					Sources: • Same as criterion 7-1 • Same as criterion 1-1
		Description: On one hand, option B1 is a central solution established by an independent third party data storage provider. On the other hand, options B2, B3 and B4 are distributed solution, which indeed include at least one conceptual "instance" of B1 acting as data storage and another central solution that manages the access between the distributed solutions. Therefore, on the basis of the number of solutions involved, we can conclude that B1 would likely be the easiest to maintain because it is a single solution. The maintenance and operation of a single storage solution is less complex than several storage solutions, even if this single solution deals with a big volume of data. The fact that B3 scores a bit lower is due to the estimated number of solutions involved.							

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		As elaborated in criterion 7-1, it is expected that B3 would include more data storage solutions than B2 and B4.						
4	**System integrity**	**10,00%**						
				100	**37,5**	**37,5**	**62,5**	
4-1	Ability to ensure the physical integrity of the system as a whole	5,00%	50,00%					Sources: • (Tanenbaum & Steen, 2006)
		Description: The physical integrity is the complete assurance that under all conditions a system is based on the logical correctness, completeness and reliability of its major assets (i.e. hardware, software and data). Alterations to a system's assets only can be made in an authorized way. According to the literature, complete physical integrity is more difficult to achieve with distributed models because there are more components involved that would need to be protected and prepared to be fault tolerant (either to external attacks or to unexpected failures). As such, B1 scores the highest and B2, B3 and B4 the lowest.							
4-2	Ability to ensure data integrity of the system as a whole (i.e. degree of minimising data inconsistencies)	5,00%	50,00%					Sources: • (Rivero & Doorn, 2002) • (Tanenbaum & Steen, 2006)
		Description: Regarding the data integrity, the same applies as with criterion 4-1. If the data is centralised (i.e. options B1 and B4), its integrity could be reinforced more efficiently than with distributed systems because: a) data verifications can be done within a database transaction in the target repository, b) no need to handle requests to remote systems, and c) overall response time of the integrity check would be lower if done within a centralised solution. These advantages become even more important when dealing with several data integrity checks per request, as it could be anticipated that it would be necessary for the Tracking and Tracing System. As such, B2 and B3, the "pure" distributed options, score the lowest. B1 scores the highest and B4 scores a bit lower than B1 because the synchronisation process may cause some problems regarding the data integrity if the integrity checks have not been done correctly prior to the synchronisation to the central repository.							
5	**System security**	**10,00%**						
				75	**75**	**75**	**75**	
5-1	Guarantee of a secure storage of the data	5,00%	50,00%					Sources: • (Rivero & Doorn, 2002) • (Tanenbaum & Steen, 2006)
		Description: To guarantee a secure storage, the solution should be secured from threats (i.e. interception, interruption, modification and fabrication) and also from attacks. B1 poses the challenge of being a single point of vulnerability. Thus, commercially sensitive information such as trade or product movements may be hacked from this central storage solution. The same challenge could be applied to B4 because there is a central surveillance solution that stores all the data as well.							

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
		Therefore, having "pure" decentralised database models, B2 and B3 achieve a better score due to the fact that such distribution of solutions minimises the impact that any attack may cause because it is unlikely that all the solutions will be launched and each distributed storage only manages a specific sub-set of data.						
5-2	Guarantee of control the access to data	5,00%	50,00%					Sources: • (Rivero & Doorn, 2002) • (OASIS SAML, 2005) • (OASIS XACML, 2013)
		Description: With regards the guarantee of control the access to data, models with a central solution (i.e. B1) can enforce security policies easier than distributed solutions (i.e. B2, B3 and B4). This is due to the fact that distributed solutions pose additional complexity (i.e. additional components in each system, interoperability of these components, handle remote requests, enable synchronisation of basic security data: users and policies, etc.) with regards the necessary federated coordination of such enforcing security policies to control of access, in comparison with a security solution configured and installed locally.						
6	**Potential of reducing illicit trade**	**20,00%**						
				100	**25**	**25**	**100**	
6-1	Potential of reducing illicit trade	20,00%	100,00%					Sources: • Same as criterion 1-1
		Description: The potential of reducing illicit trade, with regard the assessment of the data storage models, could be assimilated to the degree of effectiveness on accessing all relevant data stored to provide to the competent authorities the information needed to conduct the surveillance activities. The higher effectiveness on reading, the higher potential ability to reduce illicit trade. Hence, the weighting of this criterion is directly linked with criterion 1-1. As such, options B1 and B4 with a central database scores higher than B2 and B3.						
7	**Burden for economic stakeholders**	**10,00%**						
				62,5	**62,5**	**50**	**62,5**	
7-1	Burden for economic stakeholders	5,00%	50,00%					Sources: • Cost Analysis • (European Commission - Economic analysis of tobacco products, 2013) • Chapter 2 - Total Consumption of tobacco products as per Member State
		Description: The burden for economic operators is mainly based on the estimated costs about the infrastructure needed to host each option. It should be remarked that the costs are an estimation, based on objective assumptions. However, many things are still pending to be decided and the costs may vary. According to the cost estimation, B1 scores better (i.e. less cost) mainly because its architecture is simpler and comprises fewer systems. At the other end, the cost of B3 is						

<table>
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B3: Decentralised storage per Member State
B4: Combined storage: centralised for surveillance and decentralised for recording</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>B1</th><th>B2</th><th>B3</th><th>B4</th><th>Comments</th></tr>
<tr><td></td><td></td><td colspan="7">much higher, and as such scores the lowest. This is due to the fact that the Study assumes that 19 distributed storages would be established. At this stage, it is very difficult to anticipate which would be the most likely number of Member States willing to have their own data storage solution. For the sake of objectivity, and just for conducting the current cost estimation, this Study assumes that the number of data storages would be proportional to the consumption share per Member State at EU level. As such, since fourteen Member States have more than 2% of consumption share and a total of the 90% of EU consumption, it could be assumed that each of them would have its one repository and that another five repositories would be established, further assuming that the rest of the Member States would establish one repository to be shared by three Member States.

As per option B2 and B4, a similar assumption has been made to estimate the most likely number of repositories to be established in option B2 per manufacturer/importer. At this stage, it is very difficult to anticipate which would be the most likely number of manufacturers/importers willing to have their own data storage solution. For the sake of objectivity, and just for conducting the current costs estimation, this Study assumes that the number of data storages would be proportional to the market share at EU level. As such, since four manufacturers have 90% of EU market share, it could be assumed that each of them would have its one repository and that other three repositories would be established by the rest of manufacturers/importers, further assuming some synergies between groups of manufacturers/importers to share the repository costs because of commercial or geographical reasons.

Further details about the cost estimations, assumptions and what is included can be found in Chapter 2.</td></tr>
<tr><td rowspan="2">7-2</td><td rowspan="2">Ability to promote market competition to provide the data storage solution</td><td>5,00%</td><td>50,00%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>Sources:
• (European Commission - Economic analysis of tobacco products, 2013)
• Chapter 2 - Total Consumption of tobacco products as per Member State</td></tr>
<tr><td colspan="7">Description:
The weighting of this criterion is proportional to the number of repositories to be established by each option. This assumption is based in the fact that the more repositories to establish, the more market competition should be promoted.

Therefore, as was elaborated in criterion 7-1, this Study assumes that options B2 and B4 would establish 7 repositories, B3 would establish 19 repositories, and B1 implies only 1 repository because it is a centralised solution. Again, it should be mentioned that these numbers are an estimation and the final composition of the Tracking and Tracing Solution may vary.

Hence, according to this estimated proportionality of repositories, B3 scores the highest, and B2 and B4 score a bit lower. Option B1 has the lowest scoring because it is a central solution and only could be established by one third party data storage provider.

Notwithstanding, the selection process of the third party data storage provider shall be transparent and with the highest levels of compliance to promote trust and fair competition.</td></tr>
<tr><td>8</td><td>Burden for competent authorities</td><td>10,00%</td><td></td><td>  </td><td>  </td><td>  </td><td>  </td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>100</td><td>50</td><td>25</td><td>75</td><td></td></tr>
</table>

(B) Data Storage Models B1: Centralised storage B2: Decentralised storage per manufacturer/importer B3: Decentralised storage per Member State B4: Combined storage: centralised for surveillance and decentralised for recording								
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**B1**	**B2**	**B3**	**B4**	**Comments**
8-1	Burden for competent authorities	10,00%	100,00%					Sources: • Cost Analysis • (European Commission - Economic analysis of tobacco products, 2013) • Chapter 2 - Total Consumption of tobacco products as per Member State
		Description: The burden for competent authorities is based on the costs for competent authorities related to approval, monitoring and regularly evaluation of the contracts with the third party data storage provider(s). B1 minimises the administrative burden due to the fact that having a single solution means the following: a) there are less contracts to be monitored and approved in comparison with the decentralised options, b) there is only one number of selection processes, and c) the assessment of auditing reports is limited to only one solution. The B2, B3 and B4 models, imply additional administrative burden, in comparison with B1, due to the fact that having several solutions (i.e. with the Federation Services/surveillance solution and a group of data storage solutions) means the following: a) there are more contracts to be monitored and approved, b) the Commission shall conduct a selection process for the Federation Services/surveillance solution, and c) the assessment of auditing reports includes several solutions. As with criterion 8-2, the burden is driven by the number of repositories/solutions assumed per option, because the more solutions involved, the more administrative burden. Here it is also considered the complexity that another central sub-system could imply, as per option B4 with the surveillance solution. It should be remarked that the costs are an estimation, based on objective assumptions. However, many things are still pending to be decided and the costs may vary. Further details about the cost estimations, assumptions and what is included can be found in Chapter 2.					

Table 5: Data storage model – detailed evaluation of the policy options

1.2.3. Allowed data carriers

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
T	Grand total	100%	N/A						
				68	**84**	**81**	**86**	**54**	

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
A	**Full compliance with TPD and FCTC Protocol**	**0%**	**100%**	**100**	**100**	**100**	**100**	**100**	
A-1	Ability to contain the unique identifier and all the information specified in the article 15 of the TPD, at the unit packet level	**0%**	**100%**						Sources: • (GS1 Barcodes, 2017) • (GS1 DataMatrix, 2016) • (securPharm, 2016)
		Description: The unique identifier must include all the information required in Article 15 of the TPD. Despite the preliminary estimation made in the Interim Report I, the unique identifier sizing could be improved by certain mechanisms such as the use of look up tables for some fields or the creation of new standard traceability fields. Therefore, the data carriers selected in each alternative must fulfil this principle. The accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. A number of data carrier types able to contain the number of characters estimated to include the unique identifiers have been identified. All the options guarantee the ability to contain the unique identifier and to comply with all the requirements.								
A-2	Ability to contain the identification at the different aggregation packaging levels	**0%**	**100%**						Sources: • (GS1 Barcodes, 2017) • (GS1 DataMatrix, 2016) • (securPharm, 2016)
		Description: Article 15 of the TPD requires that the different levels of aggregation (carton, mastercase and pallet) must be identified. The creation of a unique identifier of each aggregation packaging level has been required in order to guarantee its identification as well as to facilitate the track and trace of tobacco products (each UID of aggregation packaging levels will be related with the UID of the contained aggregation packaging levels and unit packets, parent-child hierarchy). The minimum length of text to contain the identifier for aggregation packaging levels has been estimated in 25 characters (chapter 3.3.1). All the data carriers selected in each alternative must fulfil this principle. The accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. A number data carrier types able to contain the number of characters estimated to include the unique identifiers have been identified. All the options guarantee the ability to contain the unique identifier and to comply with all the requirements.								
1	**Technical feasibility**	**8.33%**	**100%**	**50**	**64**	**69**	**77**	**67**	
1-1	Ability to adapt the data carrier to the unit packet of all tobacco products.	1.39%	16.67%						Sources: • (GS1 Barcodes, 2017) • (GS1 DataMatrix, 2016) • (securPharm, 2016) • (California State Board of Pharmacy, 2013) • (everis, 2016)

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
		Description: The adaptability of the data carrier to the unit packet of tobacco products depends on the physical characteristics of the different tobacco products, the possibilities of the data carriers to be printed or affixed, the technical feasibility of the equipment to perform the printing and affixing activities (high/medium-low speed production lines) and the minimum dimensions of the data carriers to contain all the requested information (under certain conditions of readability). There have been a certain number of data carriers identified that are able to be printed or affixed on the available space of the unit packet of the different tobacco products. However, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. The option C5 obtains the highest score for this sub-criterion because it permits the use of the data carrier which adapts best to the unit packet from a set of allowed data carriers. Options C3 and C4 consider a reduced variety of data carriers (a range of approximately four types of data carrier per identification level), so the ability of the allowed data carriers to adapt to the unit packet is lowered with respect to option C5. Options C1 and C2 are more restricted in this sub-criterion because only the allowed data carrier can be adapted to all unit packets of tobacco products.								
1-2	Ability to adapt the data carrier to all the aggregation packaging levels.	1.39%	16.67%						Sources: • (GS1 Barcodes, 2017) • (GS1 DataMatrix, 2016) • (securPharm, 2016) • (California State Board of Pharmacy, 2013) • (everis, 2016)
		Description: The adaptability of the data carrier to the aggregation packaging levels of tobacco products depends of the characteristics of the different packs, the possibilities of the data carriers to be printed or affixed, the technical feasibility of the equipment to perform the printing and affixing activities and the minimum dimensions of the data carriers to contain all the requested information (under certain conditions of readability). Through literature analysis and review (GS1 General Specifications, coding rules for medicines requiring verification for the German market), a number of data carriers able to be printed or affixed in the available space of the different aggregation packages of tobacco products have been identified. However, as it was stated in the sub-criteria 1-1, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. Unlike the unit packets, the physical characteristics of the aggregation packaging levels are similar for the different tobacco products. Therefore, the ability to adapt to them is going to depend more on the available space rather than the physical characteristics of each data carrier. Options C3, C4 and C5 obtain the highest score because they permit a variety of data carriers to be adapted to the physical characteristics of the aggregation packages. Option C2 only considers a specific type of data carrier per aggregation level. Therefore some restrictions may appear to be adapted to the different packages of all the types of tobacco products. Option C1 is the more restricted alternative for this sub-criterion because it proposes the same type of data carrier for all aggregation levels, including an extra degree of complexity to adapt to the packages.								
1-3	Impact generated by the printing or	1.39%	16.67%						Sources: • (Booz | Hallen | Hamilton,

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
	affixing activities on the manufacturer and importer production processes.								2014) • (Bonaccorsi, 2012) • (McFarlane & Sheffi, 2003)
		Description: The impact on the operational processes of manufacturers depends on the ability of them to adapt their operations. There are three scenarios considered: • The economic operators already have the necessary equipment and can print or affix the data carrier with low impact. • The economic operators have similar equipment and they can adjust it to the printing or affixing of the allowed data carriers. • The economic operators do not have the necessary equipment and they need to include and implement it to their production lines. However, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. Therefore, the scoring considers the likelihood of each alternative to adapt better to the EO's preferences. The option C5 obtains the highest score, because a system that allows any existing data carrier is easier to integrate to the operations, increasing the flexibility of implementation. The options C3 and C4 consider a reduced variety of data carriers, permitting to adapt the selected data carrier to the characteristics of the production line. Options C1 and C2 are the more restricted alternatives because they consider the only allowed data carrier, increasing the impact in the EO's operations. The adaptation to the different types of production lines may be a drawback.								
1-4	Feasibility of implementing data carrier reading devices at wholesalers and distributors.	1.39%	16.67%						Sources: • (Booz | Hallen | Hamilton, 2014) • (McFarlane & Sheffi, 2003) • (EFPIA - European Federation of Pharmaceutical Industries and Associations, 2015) • (accenture, 2008)
		Description: The feasibility of implementing data carrier reading devices at the EO in the supply chain depends on the current equipment used by them in their reading operations as well as the data carriers used for track and trace purposes in the items received from their suppliers. As it was stated in sub-criterion 1-3, the accomplishment is not inherent to the number of data carriers itself but to the type of data carriers used. So the scoring considers the likelihood of each alternative to adapt better to the EO's preferences. The option C5 is one of the most restrictive because as the system enables any allowed data carrier, the EO's should be prepared to read any data carrier provided from their suppliers. However, it is contemplated the optional addition of data carrier to facilitate the reading by the EO's in the supply chain. The option C3 is equally restrictive because although the EO's have to adapt to a shorter variety of data carriers, the optionality is not considered in this alternative. The option C1 is also restrictive because it only considers a data carrier for all the identification levels, and as it was assumed in chapter 3 this cannot be a 1D data carrier, so the current installed base of the distributors in terms of scanners will be								

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
		renovated. The option C4 is more favourable because it allows a variety of data carriers and it is contemplated with the optional addition of data carriers to facilitate reading by the EOs in the supply chain. The option C2 is the most favourable because it allows only a single data carrier and also contemplates the optional addition of data carriers.							
1-5	Availability of different suppliers (with regard to third-party SW/HW components, external support, and external services).	1.39%	16.67%						Sources: • (Beil, 2009)
		Description: The availability of different suppliers depends on the number of data carriers allowed in each alternative and the type of data carriers selected. A sort range of allowed data carriers will turn in less products and technologies to be provided (equipment, printers, consumables, scanners, software…). Therefore, the availability of suppliers will be higher. As it was stated in the literature, the process of selecting a supplier is not immediate and its complexity increases when the number of allowed data carriers in the system increases. The options C1 and C2 obtain the highest score because they only consider a data carrier. Options C3 and C4 are more restrictive in regard to the availability of different suppliers because the number of allowed data carrier increases. The option C5 is the least favourable because it considers a higher number of allowed data carriers.								
1-6	Ability to adapt to quality control activities.	1.39%	16.67%						Sources: • (GS1 2D Barcode, 2015) • (GSM Barcoding, 2016) • (The Institute of Internal Auditors, 2016)
		Description: Quality is a global value that has become a major issue. In order to survive and be able to provide clients with the best products, manufacturing organisations are required to ensure that their processes are continuously monitored and the product quality is improved. The quality control activities for the data carriers are based in protocols and standards. The ability to adapt to these activities depends on the number of data carriers and the type of data carriers. The scorings for this sub-criterion are similar to 1-5 and they depend on the number of allowed data carriers. The options C1 and C2 obtain the highest score because they only consider one data carrier. Options C3 and C4 are more restrictive because they consider a higher number of data carriers and this implies a wider set of protocols and standards to be accomplished before its implementation. The option C5 is the least favourable because it contemplates a free system permitting any approved data carrier.								
2	**Interoperability**	**8.33%**	**100%**						
				100	**100**	**83**	**92**	**58**	

<table>
<tr><th colspan="10">(C) Allowed Data Carriers
C1: System with a single data carrier for all identification levels
C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels
C3: System with a limited variety of data carriers per identification level
C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels
C5: Free system allowing any existing approved data carrier</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>C1</th><th>C2</th><th>C3</th><th>C4</th><th>C5</th><th>Comments</th></tr>
<tr><td rowspan="2">2-1</td><td rowspan="2">Full interoperability with the systems of key users (i.e. competent national and European authorities).</td><td>2.78%</td><td>33.33%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Sources:
• (ISO/IEC Standardization vocabulary, 2005)
• (ITU, 2012)
• (McCathie, 2004)
• (Su, Chu, Prabhu, & Gadh, 2007)
• (Copenhagen University College of Engineering, 2008)</td></tr>
<tr><td colspan="9">Description:
‘The interoperability is conceived as the ability of two or more systems or components to exchange information and to use the information that has been exchanged’.
To support the interoperability between systems two aspects must be taken into account:
• The syntax (structure) and semantics (meaning) of the data exchanged.
• The compatibility between systems (ability of the system to read the data carrier).
The interoperability with the key users’ systems (National & European authorities) is directly influenced by the type of allowed data carriers in the system. The literature shows how the equipment may differ from one data carrier to the other.
The options C1 and C2 guarantee full interoperability because they only consider one data carrier, which can be read with a single equipment.
The options C3 and C4 also guarantee the full interoperability due to the short variety of data carriers (a range of approximately four types of data carrier per identification level).
The option C5 obtained the lowest score because it considers any approved data carriers, which considerably elevates the number of necessary devices, elevating the risk of interoperability problems.</td></tr>
<tr><td rowspan="2">2-2</td><td rowspan="2">Organisational interoperability - manufacturer & importer equipment.</td><td>2.78%</td><td>33.33%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Sources:
• (McFarlane & Sheffi, 2003)</td></tr>
<tr><td colspan="9">Description:
As it was stated for the sub-criteria 2-1, to support the interoperability between systems two aspects must be taken into account:
• The syntax (structure) and semantics (meaning) of the data exchanged.
• The compatibility between systems (ability of the system to read the data carrier).
The interoperability with the manufacturer and importer equipment is directly influenced by the number of data carriers printed or affixed in the production line, because they compromise the compatibility with the used systems.
It is assumed that only a single type of data carrier is printed or affixed in every production line in order to facilitate the interoperability with the systems and increase the production efficiency (no alterations in production due to changes in printing configuration).
Based on the conclusions made in this sub-criterion, all the options guarantee the organisational interoperability with manufacturer and importer equipment.</td></tr>
<tr><td>2-3</td><td>Organisational interoperability - wholesaler &</td><td>2.78%</td><td>33.33%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Sources:
• (McCathie, 2004)
• (Su, Chu, Prabhu, &</td></tr>
</table>

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
	distributor equipment.								Gadh, 2007) • (Copenhagen University College of Engineering, 2008)
		Description: The interoperability between distribution chain operators is imperative to efficiently keep record of the operations. This is carried out by the transmission of structured messages containing standardised and coded data. Which means that the system exchanges information electronically by using a format and a vocabulary that is readable and interpretable by the receiver. In order to do so, the compatibility between the data carriers used by the supplier and the scanning systems of the distribution chain operator is essential. The interoperability with the wholesaler and distributor equipment depends on the ability of the EOs devices to read the types of data carriers of the items provided by their suppliers. The options C1 and C2 obtain the better score because the EOs use the equipment that reads the single data carrier, or they are adapted to the optional data carriers. The option C4 is less favourable because it considers a variety of data carriers and it contemplates the optional addition of data carriers (increasing the interoperability). The option C3 is more restricted than C4 because it does not contemplate the optional addition of data carriers. The option C5 obtains the lowest score because the use of any approved data carrier may considerably affect the ability to read the codes along the supply chain operators.								
3	**Ease of operation**	**8.33%**	**100%**						
				50	**62**	**81**	**87.5**	**81**	
3-1	Impact on the operational processes of the manufacturers and importers.	2.08%	25.00%						Source: • (O'Connor, Haque, & al., 2012) • (Ivantysynova, 2008)
		Description: The impact on the operation depends on the type of new process to be implemented. These processes are integrated in the production line and require activities of maintenance and surveillance. The integration of new developments in the production activities can be a consuming process that directly affects to important factors such as cost, time and productivity. And will require a rigorous study that contemplates all the consequences associated to the decision. The option C5 obtains the highest score because it permits any approved data carrier. This facilitates the adaptation of equipment currently in use to the new demands of the production lines. Options C3 and C4 are slightly less favourable due to the more reduce set of allowed data carriers. This variety facilitates the adaptation to the different types of production lines (a range of approximately four types of data carrier per identification level). Options C1 and C2 impact the operational processes because they impose the implementation of the equipment necessary in the production lines (high/low speed) to print or affix a specific data carrier.								

<table>
<tr><th colspan="10">(C) Allowed Data Carriers
C1: System with a single data carrier for all identification levels
C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels
C3: System with a limited variety of data carriers per identification level
C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels
C5: Free system allowing any existing approved data carrier</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>C1</th><th>C2</th><th>C3</th><th>C4</th><th>C5</th><th>Comments</th></tr>
<tr><td rowspan="2">3-2</td><td rowspan="2">Impact on the operational processes of the wholesalers/ distributors/ transporters.</td><td>2.08%</td><td>25.00%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Source:
• 2D symbols in distribution and logistics GS1 (2015)
• (McFarlane & Sheffi, 2003)
• US healthcare bar code scanner acquisition criteria – GS1 Healthcare</td></tr>
<tr><td colspan="9">Description:
The impact on the operational processes for wholesalers, distributors and transporters depends on the number of devices needed to read all the data carriers associated to the items received from the supplier and the technology associated to the data carriers used (RFID technology enables the instant identification of a complete batch).
The accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used.
Option C2 obtains the highest score because it permits to read the UID with one device. Besides, the current equipment of the EO can be used.
Option C4 is less favourable because it considers a variety of data carriers, although it contemplates the optional addition of data carriers (increasing the number of necessary devices).
Option C1 contemplates only a data carrier for the unit packet and all the aggregation levels. This circumstance influences the selection of the data carrier, excluding the use of traditional 1D barcodes (widely used in supply chain operations), impacting the distribution processes.
Option C3 is more restricted than C4 because it does not contemplate the optional addition of data carriers.
The option C5 obtains the lowest score because the use of any approved data carrier may affect considerably to the number of the necessary devices to read the codes along the supply chain operators.</td></tr>
<tr><td rowspan="2">3-3</td><td rowspan="2">Impact on printing or affixing performance.</td><td>2.08%</td><td>25.00%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Source:
• (Bonaccorsi, 2012)</td></tr>
<tr><td colspan="9">Description:
The printing or affixing performance mainly depends on the equipment to perform these activities and the type of data carrier selected. As the alternatives only contemplate the number of allowed data carriers, the score is going to reflect the ability of the EOs to select the data carrier that provides better printing or affixing performance.
The quality and printing speed depends on a variety of factors such as the type of data carrier and the amount of contained information. Therefore the manufacturers will have to carefully review the characteristics of the data carriers that better adapt to their production activities. I.e. the high-speed production lines will have distinct printing necessities than medium/low-speed lines.
The options C3, C4 and C5 obtain the highest score because the EOs have the opportunity to select the data carrier that best adapts to their needs. The options presented in C4 and C5 do not affect to the scoring because there is not obligation of including additional data carriers.
The options C1 and C2 are less favourable because they only consider one data carrier, then the impact in the production line speed is remarkable.</td></tr>
<tr><td>3-4</td><td>Impact on scanning speed and reliability.</td><td>2.08%</td><td>25.00%</td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>Source:
• (National Center for Immunization and Respiratory Diseases</td></tr>
</table>

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
									Immunization Services Division, 2014) • (GS1, 2010)
		Description: The scanning speed and reliability of the scanning activities depends on the equipment and the type of data carrier selected. As the alternatives only contemplate the number of allowed data carriers, the score is going to reflect the ability of the EO's to select the data carrier that provides better scanning performance. As it was stated for the sub-criteria 3-3, it has been found that the scanning speed and reliability depends on a variety of factors such as the type of data carrier or the reading distance. Therefore, the manufacturers will have to carefully review the characteristics of the data carriers that better adapt to their production activities. The options C3, C4 and C5 obtain the highest score because the EO's have the opportunity to select the data carrier from a variety that better adapts to their production needs. The optionality presented in C4 and C5 does not affect to the scoring because there is no obligation of including additional data carriers. The options C1 and C2 are less favourable because they only consider one data carrier, which increases the impact in the production activities.								
4	**System Integrity**	**12.50%**	**100%**	**100**	**100**	**100**	**100**	**50**	
4-1	Ensure the data consistency of the system.	12.50%	100.00%						Source: • (GS1 Healthcare US, 2014) • (GS1, 2015) • (GS1 2D Barcode, 2015)
		Description: The consistency of the data carriers depends on their internal structure and how the information is disposed in application identifiers. There have been identified some organisations (i.e. GS1) that have developed standards to segment the data through application fields. The generation of the unique identifier will be based on open standards in order to facilitate the interoperability between systems, conditioning the selection of data carriers. The production identifier enables distinguishing areas such as: batch number, production date or serial number. Besides some organisations (i.e. GS1) have established some identifiers such as GTIN or GLN that enables the unique identification of items or locations. However, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. The options C1 and C2 obtain the highest score because they only allow one data carrier, which enables the use of the same application standards by means of all the data carriers, to assure the data consistency in the system. Options C3 and C4 also facilitate the interoperability because the reduced set of data carrier (a range of approximately four types of data carrier per identification level) can be based in open standards. The option C5 obtains the lowest score because it allows the use of any approved data carriers, which increases the risk related to consistency breaches in the system.								

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
5	**System Security**	**12.50%**	**100%**						
				100	**100**	**100**	**100**	**50**	
5-1	Ability to provide a secured environment for the management of data carriers.	12.50%	100.00%						Source: • (GS1 DataMatrix, 2016) • (Peris-Lopez & al., 2006) • (McCathie, 2004)
		Description: The secured environment for the management of data carriers is associated with the capacity to provide a more secured environment associated to the unauthorised manipulation, tampering or falsification of the selected data carriers. In addition, the literature has shown some types of data carriers that may include security features, reducing the risk of being falsified. As stated in the sub-criterion 4-1, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used. The options C1 and C2 obtain the highest score because they only allow one data carrier, this reduces the possibilities of falsification due to the reduced number of data carriers. Options C3 and C4 are also highly scored because the reduced set of data carriers (a range of approximately four types of data carrier per identification level) can be specifically selected to fulfil with this sub-criterion. The option C5 obtains the lowest score because it allows the use of any approved data carrier, increasing the risk associated to security features.								
6	**Potential of reducing illicit trade**	**25%**	**100%**						
				50	**100**	**100**	**100**	**50**	
6-1	Potential of reducing illicit trade	25.00%	100.00%						Source: • (European Commission - Feasibility Study, 2015) • (National Center for Chronic Disease Prevention and Health Promotion, 2016)
		Description: The potential of reducing illicit trade is directly related with the ability of each option to achieve this purpose. As stated in previous sub-criterions, the accomplishment of the sub-criterion is not inherent to the number of data carriers itself but to the type of data carriers used. This aim is related with the efficiency of the system, and the combination of sub-criterions previously stated, such as system interoperability and system security. For this purpose, it is considered that the types of allowed data carriers will challenge the objective of reducing illicit trade. The option C2 obtains the highest score because it only allows one data carrier, in turn implying the system is more efficient and enables the easier identification of potential irregularities, therefore limiting the risk. Options C3 and C4 (a range of approximately four types of data carrier per identification level) also accomplish with this sub-criterion because the short variety of allowed data carriers facilitates the correct selection.								

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
		Despite enabling the use of only one data carrier, the option C1 reduces the potential of reducing illicit trade because, as it was stated in chapter 3, the 1D data carriers for the aggregation packaging levels cannot be used. A new way of identification different from the traditional identification data carriers in transportation and logistics may generate potential disruptions in the system. The option C5 obtains the lowest score because it allows the use of any approved data carrier, which increases the risk of potential irregularities in the correct performance of the system.							
7	**Administrative/ financial burden for economic stakeholders**	**12.5%**	**100%**	 **33**	 **50**	 **50**	 **67**	 **67**	
7-1	Impact of the allowed data carriers on manufacturers & importers	4.16%	33.33%						Source: • (European Commission - Feasibility Study, 2015) • (European Commission - TPD Inception Impact Assessment, 2016)
		Description: The economic impact of the allowed data carriers on manufacturers and importers depends on the cost associated to adapt their production lines to the printing and affixing activities. It is assumed that every production line is going to print only one data carrier, and for the purpose of this study most of the economic operators have to adapt their lines. As it was stated for the sub-criteria, the cost incurred by the manufacturer depends on which of the three different scenarios is considered: • The economic operators already have the necessary equipment and can print or affix the data carrier with low impact. • The economic operators have similar equipment and they can adjust it to the printing or affixing of the allowed data carriers. • The economic operators do not have the necessary equipment and they need to include and implement it to their production lines. The cost associated to the necessary printing or affixing equipment depends on the type of data carrier. However, the objective of this work package is to decide the number of allowed data carriers. In base to all these factors, the option C5 obtains the highest score because of the ability to select the data carrier in a free system that better adapts to the production needs. Options C3 and C4 are more restricted because the range of available data carriers is more reduced (a range of approximately four types of data carrier per identification level). Finally, options C1 and C2 obtain the lowest score because of the restriction of adapting all the production processes to the printing or affixing of a determined type of data carrier.								
7-2	Impact of the allowed data carriers on wholesalers, distributors & transporters	4.16%	33.33%						Source: • (European Commission - Feasibility Study, 2015) • (GS1 Healthcare, 2009)
		Description: The economic impact of the allowed data carriers on wholesalers, distributor and							

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
		transporters depends on the cost associated to the adaptation or acquisition of reading devices. The cost of the reading device depends on the type of data carrier. As the types of data carriers are not defined in this work package, the cost is associated to the number of allowed data carriers. The option C2 obtains the better score because it only considers one allowed data carrier and the optional addition of data carrier to facilitate the reading by the EO's in the supply chain. Then the EO's can use their current equipment and reduce the cost. The option C4 is less favourable. Although it considers the optional addition of data carriers, it allows a variety of data carriers, increasing the number of data carriers to be read. The cost is raised in option C1 because the data carrier for the aggregation packaging levels cannot be a 1D data carrier. As the most used data carriers in transportation and logistics are 1D data carriers, the cost of additional scanners to be able to read the proposed data carriers is incremented. The option C3 is less favourable to the previous because it allows a variety of data carriers and the use of optional data carriers is not accepted. The worst alternative in terms of burden for wholesalers, distributors and transporters is the option C5 because it considers any approved data carrier. In this case, they have to adapt to the data carriers used in the items provided by their suppliers.								
7-3	Ability to promote market competition	4.16%	33.33%						Source: • (Council of economic advisers issue brief, 2016) • (Beck, Grajek, & Wey, 2005) • (Milne, 2013)
		Description: The weighting of this sub-criteria is proportional to the number of allowed data carriers to be established by each option. This assumption is based on the fact that the higher number of allowed data carriers, the more market competition should be promoted. Besides, the competition can lead to innovation and integration in the group of allowed data carrier of new types of technologies that could increase the efficiency of the system and the ease of operation. Therefore, the option C5 obtains the highest score because it permits any approved data carrier which facilitates and promotes the competition. Options C3 and C4 are slightly less favourable due to the more reduce set of allowed data carriers. This variety also permits the competition between a more reduce set of competitors. However, C4 scores better because the optional feature presented in the alternative may serve as stimulus for technological development. Options C1 and C2 obtain the lowest score because they impose the utilization of one type of data carrier that completely restricts the market competition.								
8	**Administrative/ financial burden for competent authorities**	**12.5%**	**100%**						
				75	**75**	**50**	**50**	**25**	
8-1	Impact of the allowed data carriers on the competent authorities	12.50%	100.00%						Sources: • (European Commission - Feasibility Study, 2015) • (GS1 Healthcare, 2009)
		Description: The economic burden for competent authorities depends on the cost of the necessary							

(C) Allowed Data Carriers C1: System with a single data carrier for all identification levels C2: System with a single data carrier per identification level and optional data carriers for aggregation packaging levels C3: System with a limited variety of data carriers per identification level C4: System with limited variety of data carriers per identification level and optional data carriers for aggregation packaging levels C5: Free system allowing any existing approved data carrier									
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**C1**	**C2**	**C3**	**C4**	**C5**	**Comments**
		equipment to correctly perform the activities of inspection and control (scanners and verification equipment). The reviewed literature has shown that there are different types of scanners that enables to read a variety of types of data carriers in function of their nature. Therefore, the impact is directly related to the number and type of data carriers. As the type of data carriers is not selected in this work package, the assessment of this sub-criterion is based on the number of allowed data carriers. The options C1 and C2 obtain the highest score because they only allow one data carrier, facilitating the operations of inspection. The options C3 and C4 are less favourable because they increase the number of allowed data carriers (a range of approximately four types of data carrier per identification level), augmenting consequently the cost associated to reading devices. There is no variation in terms of scoring for these options because the variety of allowed data carriers (not additional) is the same between them. The option that obtains the lowest score is C5 because it allows any approved data carrier, representing a higher cost associated to equipment.								

Table 6: Allowed data carriers – detailed evaluation of the policy options

1.2.4. Allowed delays in reporting events

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
T	**Grand Total**	**100%**	**N/A**				
				86	**80**	**71**	
A	**Full compliance with TPD and FCTC Protocol**	**0.00%**					
				100	**100**	**100**	
A-1	Ability of transmitting data of the entry, intermediate movements and the final exit of the unit packets of tobacco products	0.00%	50.00%				Sources: • (ISO/IEC 19987:2015 EPCIS, 2016) (GS1 System Architecture, 2016) • (WHO - FCTC, 2010) • (Rx-360 Consortium, 2014)
		Description: The solution should be based on open and mature standards, such as ISO/IEC 19987:2015 EPC Information Services. This standard specifies an abstract supply chain data model, which informs about the different events that may happen, and how information can be exchanged to be stored later. Based on this standard, the GS1 System Architecture envisages different message formats, which fit with the allowed delay options. Finally, it should be noted that many studies recommend the usage of ISO/IEC					

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
		19987:2015 EPC Information services (formerly named GS1 EPCIS) on the basis of its completeness, flexibility and proved functioning in international supply chain production systems. Therefore, if the options are based on this standard or another with the same features, this criterion could be considered fully accomplished.					
A-2	Ability of transmitting data of any transaction of tobacco products	0.00%	50.00%				Sources: • (ISO/IEC 19987:2015 EPCIS, 2016) (GS1 System Architecture, 2016) • (WHO - FCTC, 2010) • (Rx-360 Consortium, 2014)
		Description: In addition to the above, this standard also specifies how to exchange trade information to be stored later. As such, this criterion could be considered fully accomplished.					
1	**Technical feasibility**	**8.33%**					
				75	**75**	**75**	
1-1	Overall Implementation Complexity	4.17%	50.00%				Sources: • (Gustafsson, 2007) • (European Commision - Targeted stakeholder consultation TPD, 2015) (European Commission - Public consultation TPD, 2016) (European Commission - Feasibility Study, 2015)
		Description: The computational complexity of algorithms constructing a data delivery task takes into consideration several aspects, i.e., the number of CPUs, type of conditions and deadline. Option D1 demands a medium degree of system complexity in order to ensure that the whole value chain is properly adequate with the requirements of such option, including the complexity of gathering and compiling data in a shorter time, prior the reporting. Nevertheless, considering the actual technological scenario and the given period of adaptation, this complexity can be considerably mitigated, although, the other two options conclude to a low degree of complexity and are closer to the majority actual reality applied on the economic operators' data reporting, accordingly with the result of the Stakeholders Consultation Survey and with the Public Consultation, both performed during the Feasibility Study. It is important to notice that on Option D1, when too low a delay is allowed, it increases the complexity not only on the economic operator when regarding the necessary time to gather and compile the data prior being reported, but also on the Tracking and Tracing System when regarding the necessary time to validate, synchronise and process the data prior being effective and ready to be used by the competent authorities.					
1-2	Complexity on managing the volume of data on the optional Local Buffer	4.17%	50.00%				Sources: • (Gustafsson, 2007) • (Lindström & Elbushra, 2014) (Srivastava, Shankar, & Tiwari, 2012)
		Description: Prior to being reported to the Tracking and Tracing System, it is recommended that data are retained in a an optional local buffer area at the economic operators' facilities, first of all used to decouple the production process from the data reporting process, and secondly to keep the data stored prior to being reported. The optional buffer area needs can highly increase depending on the period of the retention. Therefore, the complexity of handling a lower volume of data imposed by					

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
		option 1, which can be very small and less demanding, scores a low level of complexity, whereas the other options, as the data retention time increases, the operation complexity also increases, reflected in the growth of the volume of data to be processed and transmitted in a more concentrated period of time, which leads option 2 to a high level of complexity and option 3 to a very high level of complexity. For instance, when having a one week time lag, the volume of data captured during this interval can be a thousand times bigger than when reporting on option D1, therefore, the volume of the retained data highly increases for option D3.					
2	**Interoperability**	**8.33%**		 **75**	 **81.25**	 **75**	
2-1	Impact on the economic operator's information systems	2.08%	25.00%				Sources: • (Gustafsson, 2007) • (Lindström & Elbushra, 2014) (Srivastava, Shankar, & Tiwari, 2012)
		Description: All three options offer full Interoperability with other company systems, and that applies to the need of having to be integrated with the company's systems. Option D1 demands the economic operator's system to become fully able to interact with the near real-time data requirements, which may conclude to increase the complexity to interoperate with already existing systems running on a lower level of data freshness rate, therefore, this option implies a medium impact on the economic operator's information system. Options D2 and D3 due to their longer time lag, are more capable of interoperating with the actual economic operators' information systems, implying a lower impact than option D1, although a substantial impact is not discarded.						
2-2	Ability to interoperable with any other supply chain equipment	2.08%	25.00%				Sources: • (Ross, 2015) • (European Commission - Feasibility Study, 2015)
		Description: Option D1 demands the supply chain equipment to be fully able to interact with the near real-time data requirements, which may conclude to a medium impact on the supply chain equipment. Options D2 and D3 due to their longer time lag, are more capable to interoperate with the actual manufacturers' equipment, implying both on a low impact on the supply chain equipment.					
2-3	Interoperability with the Excise Movement and Control System (EMCS)	2.08%	25.00%				Sources: • (European Commission - TPD Inception Impact Assessment, 2016) • (European Commission - TAXUD, 2006)
2-4	Interoperability with the System for Exchange of Excise Date (SEED)	2.08%	25.00%				
		Description: All three options offer full interoperability with the systems of the key users. Regardless of which option is chosen, the relationship between the competent authorities and OLAF – JRC and CHAFEA should be guaranteed. This decision point "Allowed Delays in reporting events" regards the data reporting to the tracking and tracing data storage solution. Despite that, the next step can be foreseen. When a key user's system may require to integrate with the Tracking and Tracing System, the allowed delay may impact on the interoperability if the key					

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
		user's system requires a high level of data freshness, as envisaged on the EMCS - Functional Excise System Specifications of the Taxation and Customs Union (TAXUD), which is only possible to achieve by near real-time synchronisation. Therefore option D1, due to its higher level of data freshness, is close to the optimal solution. Furthermore, option D1 can also meet the requirements of any system with lower level of data freshness needs.					
3	**Ease of operation**	**8.33%**		 **50**	 **75**	 **75**	
3-1	Impact on the operational processes of the economic operators	4.17%	50.00%				Sources: • (European Commission - Feasibility Study, 2015) (Gustafsson, 2007)
		Description: As near real-time systems evolve, the applications and operational process become more complex and require access to more data. It thus becomes necessary to manage the data in a systematic and organized fashion. In option D1, the score is impacted by the major changes on the operational processes of the economic operators, caused by the required adaptation to become ready to work with a low limited delay of data feeding process. In option D2 and option D3, minor impacts are foreseen on the operational process of the economic operators, as the one day and the one week delays allow the operational processes to proceed on a lower data feed demanding level, it is easier to be adapted.						
3-2	Need for training of the staff of the economic operators	4.17%	50.00%				Sources: • (European Commission - Feasibility Study, 2015)
		Description: As explained before, near real-time systems are more complex, thus becomes necessary longer training which implies on a medium volume of training when compared with options D2 and D3 which both imply on a low volume of training.					
4	**System integrity**	**12.50%**		 **92**	 **83**	 **67**	
4-1	Ability of providing Information Consistency	4.17%	33.33%				Sources: • (Lindström & Elbushra, 2014) • (Srivastava, Shankar, & Tiwari, 2012) • (DAMA UK Working Group, 2013) • (Veregin, 2005)
		Description: On option D1, on low limited delay process, an eventual system breakdown, communication instabilities or any other procedural point of failure, may lead to a data consistency fault that will demand a process of data validation or data recovery such as a data error detection feature. While options D2 and D3 are not so susceptible to such point of failure, as they allow the economic operator's system to have a larger time to deliver report events, the data integrity verification can be performed in a more extend time, therefore, any data inconsistency can be checked and adjusted within the allowed delay.					
4-2	Ability of providing Information Completeness	4.17%	33.33%				Sources: • (DAMA UK Working Group, 2013)

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
							• (Veregin, 2005)
		Description: Option D2 and mostly option D3 poses a problem on the Tracking and Tracing System with regards to the detection of the completeness of the events reporting cycle. A longer time lag delay allows data to be reported out of sequence, therefore, some earlier occurred event data can be reported up to one week after, while other later occurrences can be reported before, thus, the data integrity will be highly impacted until the completeness of the reporting cycle.					
4-3	Ability of providing Information Readiness and Information Effectiveness	4.17%	33.33%				Sources: • (DAMA UK Working Group, 2013) • (Veregin, 2005) • (Srivastava, Shankar, & Tiwari, 2012) • (Lebdaoui, Orhanou, & Hajji, 2013)
		Description: Option D1 is the most persistent, having a higher data transmitting rate, which leads to an optimal degree of data readiness and data effectiveness which increases the score for this option. The option D2 has a medium level of persistence leading to a lower level of data readiness and data effectiveness which concludes to a less effective approach, therefore receiving a medium score. At last, the option D3 has a very a large period of time between the event occurrence and its report, which leads to a score of low degree of data effectiveness and data readiness. This excessive large time between the event occurrence and its reporting leads to a severe lack of data readiness. However, to fulfil integrity, data must undergo many controls. Thus, additional time is needed to control and validate data. In such circumstances, information may be not available in the destination in timely fashion, thus the near real-time requirement may not be totally respected.					
5	**System security**	**12.50%**		 **87.5**	 **75**	 **62.5**	
5-1	Guarantee of control the access to the data feeding process	6.25%	50.00%				Sources: • (Lebdaoui, Orhanou, & Hajji, 2013) • (IETF TLS, 2016) • (IETF SSL, 2011) • (Berkeley University, 2016)
		Description: Option D1, has an high level of security, once having to feed near real-time data, almost no or very little data is retained in an optional buffer area, thus, prevents security violation action as such as data modification or data access. In option D2, the security level is medium, once having one day time lag to report events, the optional buffer area can become vulnerable to external attacks. In option D3, the security level is low, once having one week time lag to report events, the optional buffer area can become very vulnerable to external attacks.					
5-2	Guarantee of a secure data feeding process	6.25%	50.00%				Sources: • (Lebdaoui, Orhanou, & Hajji, 2013) • (IETF SSL, 2011) • (IETF TLS, 2016) • (Federal Information Processing Standards Publications, 2001) (Berkeley University, 2016)

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
		Description: In terms of data transmitting process the three options face the same optimal level of security, as any moving data through a network must use secure, authenticated, and industry-accepted encryption mechanisms and order security initiatives as such, data should be encrypted via application level, data traffic must be transmitted over Secure Sockets Layer (SSL), using only strong security protocols, such as Transport Layer Security (TLS), the connection between the database and application should also be encrypted using FIPS compliant cryptographic algorithms, source and target endpoints must certify the authenticity of the connection, in general, encryption should be applied when transmitting covered data between devices in protected subnets with strong firewall controls, among other security levels.					
6	**Potential of reducing illicit trade**	**25.00%**					
				100	**75**	**50**	
6-1	Potential of Reducing illicit trade	25.00%	100.00%				Sources: • Critical analysis • (European Commision - Targeted stakeholder consultation TPD, 2015) (European Commission - Public consultation TPD, 2016)
		Description: In option D1, the potential is very high, once having access to near real-time data, actions can be taken right after the event being reported and data analytics systems based on incident detection, can help authorities to prevent illicit trade. However, it will always depend on the analysis of the event patterns to find eventual pattern deviation. In option D2, the potential is lower when compared with option D1, once allowing the competent authorities to have access to the data that is almost one day old, actions can be taken only after that time lag. However, it will always depend on the analysis of the event patterns to find an eventual pattern deviation. In option D3, the potential is very low, once allowing the competent authorities to have access to one-week old data, actions can be taken only after that time lag. This becomes quite late in case an action must be taken prior a product being delivered.					
7	**Burden for economic stakeholders**	**12.50%**					
				62.5	**87.5**	**87.5**	
7-1	Impact on the cost for the operational processes to perform the Data Compilation of movements and the information about transactions.	6.25%	50.00%				Sources: • Cost Analysis • (Eurostat, 2013) • (European Commission - Feasibility Study, 2015)
		Description: As explained before, the process of an event reporting must be accomplished within the maximum allowed delay, which includes: the whole process of data capture, any internal data processing needs and/or intermediary steps through the management systems (WMS, MES, ERP, uTrack), then finally the report of the event data to the Tracking and Tracing System. The option D1 has a higher impact on the economic operator when regarding the necessary time to prepare and compile relevant data prior being reported.					
7-2	Impact on the cost of the optional local	6.25%	50.00%				Sources: • Cost Analysis

(D) Allowed Delays in Reporting Events D1: Near real-time reports D2: One-day delay reports D3: One-week delay reports							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**D1**	**D2**	**D3**	**Sources**
	storage regarding the Data Retention prior being reported to the system.						• (Eurostat, 2013) • (European Commission - Feasibility Study, 2015)
		Description: Prior to being reported to the Tracking and Tracing System, it is recommended that data are retained in an optional local buffer area, first of all used to decouple the production process from the data reporting process, and secondly to keep the data stored prior being reported. The optional buffer area needs can highly increase depending on the period of the retention. In option D1, the score positively high, concluded to a lower period of data retention, directly impacting on the local buffer, which can be very small and less demanding, whereas the other options, as the data retention time increases, the operation complexity also increases, reflexed on the growth of the volume of data to be processed and transmitted in a more concentrated period of time. For instance, when having one week time lag, the volume of data captured during this time can be thousand times bigger than when reporting on option D1, therefore, the volume of the retained data highly increases for option D3.						
8	**Burden for competent authorities**	**12.50%**		**100**	**100**	**100**	
8-1	Impact on the Competent authorities costs	12.50%	100.00%				Sources: • Cost Analysis • (European Commission - Feasibility Study, 2015)
		Description: All three options should not economically burden in any aspect the competent authorities					

Table 7: Allowed delays in reporting events – detailed evaluation of the policy options

1.2.5. Method of adding a security feature

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
T	**Grand total**	**100%**	**N/A**	**84**	**77**	**87**	
A	**Full compliance with TPD and FCTC Protocol**	**0%**	**100%**	**100**	**100**	**100**	

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
A-1	Ability to apply a security feature on all unit packets of tobacco products placed on the market, regardless of the type of product considered (e.g. cigarettes, RYO, cigars, etc.)	0%	33.3%				(European Commission - TPD Inception Impact Assessment, 2016) (everis, 2016)
		For **S1**, affixing was the main method recommended in the Feasibility Study to add a security feature to the unit packets of tobacco products (i.e. providing the security feature as a label or stamp), as it provided additional implementation flexibility, choice of security elements and compatibility with both high speed and low volume tobacco production volume over direct marking, Feasibility Study (European Commission - Feasibility Study, 2015, p. 243) The affixed security features can also be integrated onto national tax stamps. During Work Package 1 of the Implementation Study, 22 Member States were researched with respect to their use of overt, covert and semi-covert security features (these elements are almost all related to the use of current cigarette and tobacco tax stamps). Out of the 22 Member States studied: 1. 15 of them already have a visible Unique Identification Number as part of the security feature and 1 Member State has an invisible (covert) Unique Identification Number (thus, of those studied, 73% already use visible or invisible Unique Identification Numbers); 2. 4 Member States studied use a visible (overt) 2D barcode or matrix on the tax stamp (with 1 Member State using a QR code and the 3 others using a 2D matrix) and 1 Member State uses a covert (invisible) 2D matrix code (thus, of those studied, 23% use a visible or invisible 2D barcode) (everis, 2016, p. 45) Also, the application of stamps is possible for the full scope of manufacturing processes, as automated and high volume production lines and imported goods can be labelled at the manufacturing site abroad and low volume production lines can be labelled manually, Feasibility Study (European Commission - Feasibility Study, 2015, p. 242) Regarding **S2**, before choosing to affix the security features, the Feasibility Study also considered (1) including the security feature in the commercial packaging, (2) including the security feature in specific packaging elements (e.g. clear wrap), (3) direct printing of the security feature, and (5) combining the security feature with fingerprinting, Feasibility Study (European Commission - Feasibility Study, 2015, p. 240) Out of these, the Implementation Study considered option (2) as not compliant with Article 16 of the TPD (the Feasibility Study had already expressed some concerns) D1-TTIS-Interim_Report_I (everis, 2016, p. 47); Feasibility Study (European Commission - Feasibility Study, 2015, p. 241) This way, the analysis still leaves as possible methods to add a security feature onto unit packets of tobacco products: (1) included in the commercial packaging, (3) printed directly, or (5) combined with fingerprinting. These three methods can be roughly translated into 'Printing or integrating through a different method'. For **S3**, with option 'Mixed solution' the choice lies between affixing or printing or integrating through a different method. According to the explanation presented before, both options can be applied on all unit packets of tobacco products placed on the market, regardless of the type of product considered (e.g. cigarettes, RYO, cigars, etc.).						
A-2	Ability to combine visible and invisible elements on the security feature	0%	33.3%				(European Commission - Feasibility Study, 2015) (everis, 2016)
		For **S1**, the Feasibility Study had already considered the need to apply visible and invisible elements on the security feature. After defining that the security features would be affixed, one of its high level conclusions was that "there are a considerable					

<table>
<tr><th colspan="8">(S) Method of adding a security feature
S1: Affixing
S2: Printing or integrating through a different method
S3: Mixed solution</th></tr>
<tr><th>ID</th><th>Evaluation parameters</th><th>Global Weight</th><th>Element Weight</th><th>S1</th><th>S2</th><th>S3</th><th>Sources</th></tr>
<tr><td></td><td></td><td colspan="6">number of overt (i.e. visible), covert (i.e. invisible) and forensic security elements that can be combined to create a competent security feature as contemplated in Article 16" of the TPD. This way, one can conclude that both visible and invisible elements can be included in an affixed security feature, Feasibility Study (European Commission - Feasibility Study, 2015, p. 259)

This was also concluded during the analysis of Member States' use of overt, covert and semi-covert security features (Mainly on tax stamps), where it was possible to identify the utilisation of overt and covert features in many situations D1-TTIS-Interim_Report_I (everis, 2016, p. 44).

The Feasibility Study also provides a review of the main technological options for overt, semi-covert, and covert security features, (European Commission - Feasibility Study, 2015, p. 72)

For S2, when printing or integrating through a different method, and especially if the security features are included in the commercial packaging, this provides for an easy option for some covert and forensic elements to be introduced across multiple areas of the packaging, Feasibility Study (European Commission - Feasibility Study, 2015, p. 240)

There are also some security features specifically related with direct printing techniques, such as intaglio printing, flexography, guilloche, and micro printing.

However, these techniques take advantage of specific characteristics and capabilities of the very large, precise and expensive printing equipment operated by security printers and are therefore not generally available commercially or to the public, Feasibility Study (European Commission - Feasibility Study, 2015, p. 77)

For S3, regardless the method chosen to add a security feature, it will always be possible to combine visible and invisible elements on the security feature.</td></tr>
<tr><td rowspan="2">A-3</td><td rowspan="2">Guarantee that the security feature is tamper proof and irremovable</td><td>0%</td><td>33.3%</td><td>  </td><td>  </td><td>  </td><td>(European Commission - Feasibility Study, 2015)</td></tr>
<tr><td colspan="6">For S1, affixed papers or stamps are not "naturally" tamper proof or irremovable. This was the main concern expressed on the Targeted Stakeholder Consultation. According to the respondents, this solution protects only the paper itself, and not the pack, and has proved to be easily circumvented, as happens today with tax stamps , Feasibility Study (European Commission - Feasibility Study, 2015, p. 75)

This being said, there are ways of making an affixed security feature tamper proof and irremovable. The most common response to this need in tobacco products is by using a cellophane wrap with a tear strip, but this is not possible to all types of tobacco products.

There are also specific methods to add tamper resistance to an affixed security feature, such as:

1. Mixing strong and weak elements into the combination of materials (substrates) and bond layers (e.g. the adhesive or method by which the security feature is affixed). The most common way of deploying this method is by using frangible paper. In labelling, frangible paper is used to make thin, delicate face materials for tamper evident labels. These materials have very little internal strength and structural integrity, meaning that if someone attempts to remove a label from a substrate, it will fragment into tiny pieces, which makes it extremely difficult to remove the label in its entirety and provides visual evidence that someone has attempted to tamper with it.

2. Micro cuts/ die cuts that create a weakness in the materials in the feature that are damaged during attempted removal. Alternatively, soluble or chemical sensitive materials may be included in the substrate that dissolve and stain the security feature should it come into contact with solvents or liquids that may be used during tampering attempts. An example may be including a chemical that reacts and changes colour in the presence of solvents that may be applied by attackers attempting to remove the security feature to reuse on fraudulent packs</td></tr>
</table>

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
		Feasibility Study (European Commission - Feasibility Study, 2015, p. 75) These methods may come with an extra cost, but they guarantee that the affixed security features are tamper proof and irremovable. The utilisation of frangible paper and die cuts (kiss cuts) was also a premise in all four options defined for Security features in the Feasibility Study, Feasibility Study (European Commission - Feasibility Study, 2015, p. 242) (European Commission - Feasibility Study, 2015, p. 251) (European Commission - Feasibility Study, 2015, p. 252) (European Commission - Feasibility Study, 2015, p. 256) In opposition, concerning **S2**, printing or integrating through a different method guarantees that the security feature is physically printed or integrated through a different method on the packaging material, and cannot be removed and reapplied on another product, Feasibility Study (European Commission - Feasibility Study, 2015, p. 241) The respondents of the Targeted Stakeholders Consultation actually went a step further, and recommended the utilisation of security features applied directly onto the pack, such as fingerprinting, digital taggants, invisible inks, and RFID tags D1-TTIS-Interim_Report_I (everis, 2016, p. 27) For **S3**, the respondents of the Targeted Stakeholders Consultation also noted that given the existence of smaller manufacturers of tobacco products, it is also recommended to allow for some flexibility on the security features defined. This way, these smaller manufacturers could use an affixed feature, for instance, that would be adaptable to the specifications of their packaging D1-TTIS-Interim_Report_I (everis, 2016, p. 27)						
1	**Technical feasibility**	**8.33%**	**N/A**	 **75**	 **75**	 **81.3**	
1-1	Ability to produce/ apply the security features with a minimal impact on the manufacturers' production process	4.17%	50.0%				(European Commission - Feasibility Study, 2015) (everis, 2016)
		For **S1**, the similarity between affixing a security feature and the method currently used for tax stamps means that this equipment can be used with existing processes and equipment that can potentially be leveraged. It is also important to notice that 22 out of 28 Member States currently apply fiscal marks in the form of tax stamps, and that as this is a proven model, the 6 Member States that currently do not have tax stamp programmes can implement this model to affix security features, without any fiscal objectives, D1-TTIS-Interim_Report_I (everis, 2016, p. 44) As a downside, affixing a security feature requires an additional station on the tobacco production lines, which places this process on the critical path, and any label/ stamp defects or problems create the risk of causing production downtime, Feasibility Study (European Commission - Feasibility Study, 2015, p. 242) Regarding **S2**, installation of equipment to print or integrate a security feature through a different method in a production line can be intrusive, and the installations have to be supported by a maintenance team for on-going equipment and production support. Also, some limitations may be applicable for operation of the solution on production lines outside of the EU where there may be no legal basis to require access and control of the equipment, Feasibility Study (European Commission - Feasibility Study, 2015, p. 241) For **S3**, the application of security features will always generate an impact on the manufacturers' production process, but this option guarantees a degree of flexibility that makes its implementation possible to all types of tobacco products.						

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
1-2	Ability to outsource the production of security features with a minimal impact on the manufacturers' production process	4.17%	50.0%				(European Commission - Feasibility Study, 2015) (Member States representatives, 2016)
		Concerning **S1**, and where applicable, the competent authorities outsource the production of tax stamps, which are produced by a security printer, separate from the commercial processes used to produce the tobacco packaging, Member States Interviews (Member States representatives, 2016) This way, security printers are used to handle sensitive material like papers, security elements, security inks, and semi-finished and finished goods. Certification and compliance requirements require all steps of the production to be documented including material balance, batches, and waste, Feasibility Study (European Commission - Feasibility Study, 2015, p. 242) In this model, the security features would then be shipped to the tobacco manufacturers that would affix them onto unit packets of tobacco products. Regarding **S2**, when assessing the ability to outsource the production of security features, one is considering to include the security feature in the commercial packaging. In this case, and as the security elements are incorporated as part of the packaging production process, there is no downstream impact on the manufacturers' production process. On the downside, outsourcing the production makes it more difficult to control and audit all the involved printers and the supply chain of these security elements and/or security inks and the finished printed packaging. Also, it is difficult to maintain control and protection of the secrecy of the security feature. There is also the fact that, generally, the processes at non-security printers are less strict and there is less need for documentation of material balance and waste. For this method to be possible, the security features need to be designed to be compatible with a large variety of different printing machines that may be used, Feasibility Study (European Commission - Feasibility Study, 2015, p. 240) With '**S3**: Mixed solution', a manufacturer can outsource the production of the security features, and then apply them onto the unit packets of tobacco products (if necessary). This way, the tobacco manufacturers can work to minimise the impact on their production process.					
2	**Interoperability (with key users' and other company's systems)**	**8.33%**	**N/A**	 **100**	 **100**	 **100**	
2-1	Interoperability between competent authorities and their testing labs and the testing capabilities provided by OLAF - JRC	2.78%	33.3%				(Member States representatives, 2016)
		All options guarantee the same level of interoperability between the competent authorities and OLAF - JRC, as the interoperability is evaluated at security feature level, and not through its method of application. It was also shared by some Member States' representatives, during the consultations performed, that they have already sent some packages to be tested by OLAF-JRC lab (Estonia) Member States Interviews (Member States representatives, 2016) while others plan to use it for independent testing (Croatia and Spain) (Member States representatives, 2016) In any case, when this topic came up during our interviews, this options was widely recognised as value added, as it enables to perform tests					

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
		independently from the industry.					
2-2	Ensure that the security features can be read and tested by the competent authorities	2.78%	33.3%				(European Commission - Feasibility Study, 2015)
		The reading/ scanning and testing of the security features is related with the specific security elements implemented on the unit packets of tobacco products, and not with its method of application. This being said, there are multiple ways to authenticate a security feature by the competent authorities, and whichever security elements are implemented, they need to be given access to them: 1. Naked eye or mobile phone: Methods used to verify the visible elements and get information in the field about the product and verify the origin. 2. Yes/ No devices: Devices that provide immediate answer (Yes or No) on the presence or not of specific markers (covert feature) incorporated as part of the security feature. 3. Dedicated electronic devices: More reliable than mobile phone, these devices feature specific functionalities allowing further information for enhanced verification. These devices can take various forms, and can include PC accessories devices (e.g. readers, scanners or microscope cameras), add-on hardware for mobile commercial devices, or self-contained proprietary hand-held devices. 4. Filter, UV lamp, magnifier: Used by the competent authorities to verify semi-covert security features. 5. Laboratory equipment: Use of knowledge and dedicated scientific methods to validate the authentication elements or intrinsic properties of the material good. To be acceptable by a legal authority, forensic evidence may need to be established by a trusted third party, Feasibility Study (European Commission - Feasibility Study, 2015, p. 78)					
2-3	Interoperability between the digital elements of security features and the industry systems	2.78%	33.3%				(European Commission - Feasibility Study, 2015)
		The Feasibility Study considered the industry's suggestion to use serialisation (i.e. tracking and tracing solution) as the means to determine if a tobacco product is legitimate and to consider the unique identifier as an overt security element. Considering that this was not enough, the Feasibility Study team then proposed a number of security elements to supplement the unique identifier, in order to increase the strength of the overall security feature Feasibility Study (European Commission - Feasibility Study, 2015, p. 251) Taking this information into consideration, in case one wants to consider serialisation as a security feature, there needs to be integration with the industry systems, as per the tracking and tracing solution. This integration, however, is required whichever method of adding a security feature is chosen, and should already be considered in the data carrier implemented.					
3	**Ease of operation**	**8.33%**	**N/A**				
				87.5	**75**	**87.5**	
3-1	Impact on the operational processes of the manufacturers	8.33%	100%				(European Commission - Feasibility Study, 2015)
		Regarding **S1**, an affixed security feature has the advantage that the practice of application of stamps during the manufacturing process is known and generally					

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
		accepted within the industry. Also, the control of the affixed stamps provides for an accurate volume verification, which is important for reconciling the integrity of the overall tobacco traceability system (the number of security features affixed matches the number of unique identifiers generated and verified). As a downside, using affixed security features requires the manufacturers to manage their quantities of labels/ stamps on hand, and to ensure these are stocked in the label applicator equipment ahead of production runs Feasibility Study (European Commission - Feasibility Study, 2015, p. 245) For **S2**, in case the security feature is directly printed or integrated through a different method, there is the opportunity to perform some volume control (based on volume of security inks used). This being said, adding security features directly on the tobacco packaging is intrusive for the packaging design and all the brands will have to adapt their designs to incorporate the security feature , Feasibility Study (European Commission - Feasibility Study, 2015, p. 244) In case the production is outsourced, however, this method enables to incorporate all security elements as part of the packaging production process, with no downstream impact on the tobacco manufacture process, Feasibility Study (European Commission - Feasibility Study, 2015, p. 240) On **S3**, regardless the method chosen, there is always the possibility to generate an impact on the operational processes of the manufacturers. The possibility of choosing the method of application brings an additional layer of flexibility which enables the manufacturers to minimise the impacts generated.					
4	**System integrity**	**12.50%**	**N/A**	 **80**	 **75**	 **87,5**	
4-1	Guarantee the integrity of the system when the security features are diverted from their intended use	12.50%	100%				(everis, 2016)
		The solution providers recommend that the security features consider the mass operations at stake across the EU. Their robustness and practicality should be equivalent to what is used for fiduciary, identity and value documents (e.g. passports, currencies, etc.). In addition, a combination of overt, semi-covert and covert security features is needed in order to provide the appropriate protection against fake products, and to allow easy authentication, D1-TTIS-Interim_Report_I (everis, 2016, p. 27) For **S1**, during the Targeted Stakeholder Consultation, some stakeholders consider that paper-based security features are easy to copy, and once copied, they create a false sense of security that the product they are applied to is genuine. Plus, these can be lost or stolen and then applied to illegal products with the same effect D1-TTIS-Interim_Report_I (everis, 2016, p. 27)These critics are true, to some extent, but in the event of having security features diverted from their intended use, there are controls than can be put in place on their supply chain to minimise the impact on the integrity of the system. On **S2**, instead of affixed security features, some stakeholders recommend the utilisation of new technologies which enable the authentication of products based on the individual physical properties of the packaging material (e.g. fingerprinting) although it is considered hard to assure the integrity of the packs. With '**S3**: Mixed solution, the security feature can be affixed and/or printed or integrated through a different method in a combination of overt, semi-covert and covert security features in order to provide the appropriate protection against counterfeited products and to allow easy authentication [RS35].					

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
5	**System security**	**12.50%**	**N/A**	**75**	**75**	**75**	
5-1	Guarantee of a secure environment for the production of security features	4.17%	33.3%				(European Commission - Feasibility Study, 2015)
		There are always risks on the production of security features, whether this is performed by the industry or by a third party. However, there are several controls that can be implemented and that can be relevant for the security feature described in Article 16, such as: 1. Production should take place in a secure, controlled environment with appropriate security measures in place to protect the premises against unauthorised access. 2. Establishing controls for full accountability over the security materials used in the production of the security feature. This should include a full reconciliation at each stage of the production process with records maintained to account for all security material usage. The audit trail should be to a sufficient level of detail to account for every unit of security material used in the production and should be independently audited by persons who are not directly involved in the production. 3. Records should be certified at a level of supervision to ensure accountability should be kept of the destruction of all security waste material and spoiled security feature items. 4. Materials used in the production of the security feature should be of controlled varieties where applicable, and obtained only from reputable security materials suppliers. Materials whose use is restricted to high security applications should be used, and materials that are available to the public on the open market should be avoided. 5. Knowledge of the covert security feature elements should be restricted and disclosed on a "need-to-know" basis, Feasibility Study (European Commission - Feasibility Study, 2015, p. 243)					
5-2	Guarantee of a secure transport of the security features/ necessary supplies	4.17%	33.3%				(European Commission - Feasibility Study, 2015)
		There are currently secure supply chain logistics for both inputs to the security feature, and control of storage and distribution itself. These can be maintained to guarantee the secure transport of the security features and/or the necessary supplies to the manufacturers' facilities, Feasibility Study (European Commission - Feasibility Study, 2015, p. 245)					
5-3	Guarantee of a secure storage of the security features/ necessary supplies	4.17%	33.3%				(European Commission - Feasibility Study, 2015)
		Tax stamp ordering and logistics processes that provide control of labels/ stamps of value are currently established and in operation in most Member States today and can serve as a model for security features. Manufacturers operating in the EU would already be familiar with these processes, and can manage the receipt, storage and waste management of the affixed security features elements. It is anticipated that as the distribution model has already been proven, that the logistics infrastructure could be setup in those four Member States that do not currently have tax stamp programmes, Feasibility Study (European Commission - Feasibility Study, 2015, p. 248)					
6	**Potential of reducing illicit**	**25.00%**	**N/A**				

(S) Method of adding a security feature S1: Affixing S2: Printing or integrating through a different method S3: Mixed solution							
ID	**Evaluation parameters**	**Global Weight**	**Element Weight**	**S1**	**S2**	**S3**	**Sources**
	trade			**75**	**50**	**100**	
6-1	Potential of reducing illicit trade	25.00%	100%				(everis, 2016)
		Regarding **S1**, in the Targeted Stakeholder Consultation, some stakeholders expressed concerns regarding having an affixed security feature. According to them, stamps are generally considered easy to counterfeit (as only one element, the stamp, needs to be counterfeited). For this reason the use of stamps requires controls during the production, supply and storage (which presents a high risk if printing is allowed in production facilities located outside the EU), and it introduces a new risk regarding the use of authentic stamps stolen or fraudulently supplied on counterfeit products, D1-TTIS-Interim_Report_I (everis, 2016, p. 27) For **S2**, there are many advantages of using printing or integrating through a different method, although, for instance and as an example, special fibres in the paper that react to UV light will be all over the Unit packet and will be difficult to determine if it is a genuine Unit packet or a counterfeit Also, modern technologies should be fostered. There are many technologies ready for implementation, such as digital fingerprinting, digital taggants, traditional taggants printed or sprayed over products, invisible printing, among others, D1-TTIS-Interim_Report_I (everis, 2016, p. 27) On **S3**, flexibility seems to be the key to ensure a maximum reduction of illicit trade. Since there are many tobacco products, the security features should be adapted to their material and packaging (e.g. cigarette packs are made of paper, RYO is sold in pouches of plastic or tins of aluminium, cigars are sold in wood boxes, etc.). These materials call for different application methods, but also offer different possibilities for securing the products, D1-TTIS-Interim_Report_I (everis, 2016, p. 27)					
7	**Burden for economic stakeholders**	**12.50%**	**N/A**	 **100**	 **25**	 **100**	
7-1	Burden for economic stakeholders	12.50%	100%				N/A
		The options (S1) and (S3) have a cost of approximately 15 M€ per year and they do not have a significant difference between them. With a cost 75 M€/year, option **S2** has the highest burden for economic stakeholders, and so, the lowest score. The detailed cost analysis can be found on Chapter 2.					
8	**Burden for competent authorities**	**12.50%**	**N/A**	 **100**	 **100**	 **100**	
8-1	Burden for competent authorities	12.50%	100%				N/A
		No burden on competent authorities is considered, as all the controls performed by the competent authorities are considered under A. Governance model. It is possible for Member States to aggregate the security features as envisaged in the Article 16 of the TPD with the national tax stamps (where applicable). However, this is a choice of each Member State, which falls off the scope of this exercise.					

Table 8: Method of adding a security feature – detailed evaluation of the policy options

2. ASSESSMENT FOR THE CALCULATION OF THE COST-BENEFIT ANALYSIS

The cost-benefit analysis (European Commission - DG REGIO, 2014) is an analytical instrument for judging the economic and social advantages or disadvantages of an investment decision by assessing its costs and benefits and thus estimating the impact attributable to it. It is based on the methodology presented in the "Guide to Cost-Benefit Analysis of Investment Projects" created by the European Commission to assess investment projects.

This annex is comprised of three main parts that assess the calculation of the cost-benefit analysis:

- Detailed calculation of the benefits
    - The benefit assessment distinguishes between the economic benefits (revenues from increase in legal sales and other socio-economic benefits) and the social and environmental benefits (people who will reduce or quit smoking, reduction of premature mortality cost due to smoking and other social and environmental benefits).
- Detailed calculation of the costs
    - The cost assessment describes the capital and operational expenditures for the project lifetime.
- Financial, sensitivity and statistical analyses:
    - Verify the financial sustainability of the project.
    - Identify the critical variables of the project and estimate the impact they have in the financial results.
    - Estimate the evolution of the financial impact for uncertainties in the system.

2.1. Detailed calculation of the benefits

2.1.1. Assessment for the calculation of economic benefits

The estimation of the market size, both legal and illicit, is based on the TPD Inception Impact Assessment (European Commission - TPD Inception Impact Assessment, 2016). This report estimates the manufactured cigarette consumption in 25 Member States (Malta, Luxemburg and Cyprus). The legal consumption for these countries has been estimated by reviewing the legal consumption per capita (World Lung Foundation, 2015). As there has not been found data available regarding the illicit consumption in those countries, the percentage of illicit consumption is estimated as the average for the rest of the countries in the EU, 11.26%

	Consumption breakdown			
	Total Legal Consumption (Millions of unit packets)	Illicit Consumption (Millions of unit packets)	Total Consumption (Millions of unit packets)	Percentage of Illicit Consumption (%)
	(A)	(B)	(C) = (A) + (B)	(D) = (B) / (C)
Austria	683.45	124.20	807.65	15.38%
Belgium	525.40	43.14	568.54	7.59%
Bulgaria	545.75	62.13	607.87	10.22%
Croatia	276.60	56.54	333.13	16.97%
Cyprus	69.85	8.86	78.71	11.26%
Czech Republic	945.11	108.82	1,053.92	10.32%
Denmark	282.11	3.83	285.94	1.34%
Estonia	93.85	21.07	114.92	18.33%
Finland	211.49	17.83	229.32	7.78%
France	2,269.29	450.00	2,719.29	16.55%
Germany	4,001.43	356.74	4,358.17	8.19%
Greece	839.51	234.15	1,073.66	21.81%
Hungary	387.27	46.41	433.68	10.70%
Ireland	152.23	44.70	196.93	22.70%
Italy	3,588.70	220.74	3,809.44	5.79%
Latvia	96.28	43.03	139.31	30.89%
Lithuania	155.49	37.95	193.44	19.62%
Luxembourg	63.93	8.11	72.04	11.26%
Malta	27.22	3.45	30.67	11.26%
Netherlands	536.97	37.90	574.87	6.59%
Poland	2,059.07	364.32	2,423.39	15.03%
Portugal	399.66	48.44	448.10	10.81%
Romania	1,044.81	191.18	1,235.99	15.47%
Slovakia	346.27	34.71	380.97	9.11%
Slovenia	186.70	22.68	209.38	10.83%
Spain	2,492.67	264.23	2,756.89	9.58%
Sweden	300.27	35.00	335.27	10.44%
United Kingdom	1,814.46	205.90	2,020.36	10.19%
Total	**24,395.80**	**3,096.01**	**27,491.81**	**11.26%**

Source:
(A): (Directive 2014/40/EU of the European Parliament and of the Council, 2014)
(B): (World Lung Foundation, 2015)

Table 9: Consumption breakdown – Detailed calculation

The report further divides the illicit consumption into illicit whites, counterfeit, and other illicit trade, which was assumed to be 100% contraband for the purpose of the calculations (Transcrime, Joint Reaseach Centre on Transational Crime, 2015).

	Illicit Consumption					
	Percentage of Illicit Whites (%)	Percentage of Counterfeit (%)	Percentage of Contraband (%)	Illicit Whites Consumption (Millions of unit packets)	Counterfeit Consumption (Millions of unit packets)	Contraband Consumption (Millions of unit packets)
	(E)	(F)	(G)	(H) = (B) · (E)	(I) = (B) · (F)	(J) = (B) · (G)
Austria	9.30%	4.10%	86.60%	11.55	5.09	107.56
Belgium	11.00%	6.60%	82.40%	4.74	2.85	35.54
Bulgaria	42.50%	0.00%	57.50%	26.40	0.00	35.72
Croatia	92.20%	2.50%	5.30%	52.13	1.41	3.00
Cyprus	6.40%	0.00%	93.60%	0.57	0.00	8.30
Czech Republic	32.90%	42.70%	24.40%	35.80	46.46	26.55
Denmark	0.70%	3.50%	95.80%	0.03	0.13	3.66
Estonia	54.70%	3.50%	41.80%	11.52	0.74	8.81
Finland	2.90%	0.40%	96.70%	0.52	0.07	17.24
France	12.80%	1.40%	85.80%	57.60	6.30	386.10
Germany	10.80%	5.00%	84.20%	38.53	17.84	300.38
Greece	63.50%	0.60%	35.90%	148.69	1.40	84.06
Hungary	58.90%	3.60%	37.50%	27.33	1.67	17.40
Ireland	20.70%	4.60%	74.70%	9.25	2.06	33.39
Italy	32.30%	9.90%	57.80%	71.30	21.85	127.59
Latvia	70.60%	1.00%	28.40%	30.38	0.43	12.22
Lithuania	76.30%	0.20%	23.50%	28.95	0.08	8.92
Luxembourg	24.60%	0.00%	75.40%	2.00	0.00	6.12
Malta	55.20%	1.00%	43.80%	1.91	0.03	1.51
Netherlands	4.00%	2.50%	93.50%	1.52	0.95	35.44
Poland	58.00%	19.30%	22.70%	211.30	70.31	82.70
Portugal	19.50%	26.40%	54.10%	9.45	12.79	26.21
Romania	25.20%	17.30%	57.50%	48.18	33.07	109.93
Slovakia	78.80%	11.20%	10.00%	27.35	3.89	3.47
Slovenia	30.20%	10.60%	59.20%	6.85	2.40	13.43
Spain	44.60%	2.30%	53.10%	117.84	6.08	140.30
Sweden	11.80%	5.30%	82.90%	4.13	1.86	29.02
United Kingdom	19.20%	4.30%	76.50%	39.53	8.85	157.51
Total	**34.63%**	**6.78%**	**58.59%**	**1,025.33**	**248.62**	**1,822.06**
Source: (E), (F), (G): (Transcrime, Joint Reaseach Centre on Transational Crime, 2015)						

Table 10: Illicit consumption – Detailed calculation

From this, it is possible to see the numbers on the division of illicit consumption:

- Illicit whites (1,025.33 million unit packets)
- Counterfeit (248.62 million unit packets)
- Contraband (1,822.06 million unit packets)

It is assumed that there will be a reduction of illicit trade to the order of 30% for contraband, 10% for counterfeit, and 10% for illicit whites (European Commission - Feasibility Study, 2015). Mapping the values presented for illicit trade with the baseline reduction, it is possible to quantify the total impact on the tobacco products market.

	Estimated impact on illicit trade reduction					
	Reduction in consumption of illicit whites (Millions of unit packets)	Reduction in consumption of counterfeit (Millions of unit packets)	Reduction in consumption of contraband (Millions of unit packets)	Reduction in illicit consumption (Millions of unit packets)	Percentage of reduction in Illicit Trade (%)	Percentage of reduction in Total Consumption (%)
	(K) = (H) · 10%	(L) = (I) · 10%	(M) = (J) · 30%	(N) = (K) + (L) + (M)	(O) = (N) / (B)	(P) = (N) / (C)
Austria	1.16	0.51	32.27	33.93	27.32%	4.20%
Belgium	0.47	0.28	10.66	11.42	26.48%	2.01%
Bulgaria	2.64	0.00	10.72	13.36	21.50%	2.20%
Croatia	5.21	0.14	0.90	6.25	11.06%	1.88%
Cyprus	0.06	0.00	2.49	2.55	28.72%	3.23%
Czech Republic	3.58	4.65	7.97	16.19	14.88%	1.54%
Denmark	0.00	0.01	1.10	1.12	29.16%	0.39%
Estonia	1.15	0.07	2.64	3.87	18.36%	3.37%
Finland	0.05	0.01	5.17	5.23	29.34%	2.28%
France	5.76	0.63	115.83	122.22	27.16%	4.49%
Germany	3.85	1.78	90.11	95.75	26.84%	2.20%
Greece	14.87	0.14	25.22	40.23	17.18%	3.75%
Hungary	2.73	0.17	5.22	8.12	17.50%	1.87%
Ireland	0.93	0.21	10.02	11.15	24.94%	5.66%
Italy	7.13	2.19	38.28	47.59	21.56%	1.25%
Latvia	3.04	0.04	3.67	6.75	15.68%	4.84%
Lithuania	2.90	0.01	2.68	5.58	14.70%	2.88%
Luxembourg	0.20	0.00	1.84	2.03	25.08%	2.82%
Malta	0.19	0.00	0.45	0.65	18.76%	2.11%
Netherlands	0.15	0.09	10.63	10.88	28.70%	1.89%
Poland	21.13	7.03	24.81	52.97	14.54%	2.19%
Portugal	0.94	1.28	7.86	10.09	20.82%	2.25%
Romania	4.82	3.31	32.98	41.10	21.50%	3.33%
Slovakia	2.73	0.39	1.04	4.16	12.00%	1.09%
Slovenia	0.68	0.24	4.03	4.95	21.84%	2.37%
Spain	11.78	0.61	42.09	54.48	20.62%	1.98%
Sweden	0.41	0.19	8.70	9.30	26.58%	2.77%
United Kingdom	3.95	0.89	47.25	52.09	25.30%	2.58%
Total	**102.53**	**24.86**	**546.62**	**674.01**	**21.77%**	**2.45%**

Table 11: Estimated impact on illicit trade (I) – Detailed calculation

Assuming a reduction of illicit trade of 30% for contraband, 10% for counterfeit, and 10% for illicit whites, the solution can reduce the illicit market with a net effect of 2.45%, which translates into 674.01 million packs.

This reduction in illicit trade results in one of two possible effects:

- An increase of the sales in the legal market, and/or;
- A portion of the smokers will reduce consumption, or even quit smoking.

In order to model the effects of the reduction in illicit trade the concept of price elasticity (Berliant & Raa, 1988) (Anderson, McLellan, Overton, & Wolfram, 1997) (defined as the measurement of how responsive an economic variable is to a change in another) is applied to the analysis. It represents the responsiveness of the quantity of tobacco products demanded, to a change in price.

ESTIMATION OF PRICE ELASTICITY AND COST OF ILLICIT TOBACCO PRODUCTS

After a deep review of the literature (Tennant, 1950) (Reed, 2010) (Joossens, Ross, Merriman, & Raw, 2009), research has consistently demonstrated that increases in the price of tobacco products are followed by moderate falls in the consumption (reduction in the percentage of consumers and reduction in the number of tobacco products available on the market) (World Bank, 1999) (International Agency for Research on Cancer, 2011) (The cancer council, 2017).

A study conducted by the International Agency for Research on Cancer in 2011 (International Agency for Research on Cancer, 2011) estimates the average price elasticity for high-income countries is about -0.4, ranging between -0.2 and -0.6. Another source, a World Bank review (World Bank, 2016) (Jha & Chaloupka, 2000), concluded that the price elasticity varies from –0.3 and -0.5 in developed countries, while the average price elasticity in developing countries stands at around -0.8. Therefore, it can be stated that the demand in countries with a lower purchasing power is more elastic than the demand in wealthier countries.

Based on these conclusions the price elasticity per country in Europe has been estimated according to GDP per capita in Purchasing Power Standards (PPS), where the average of EU28 is set to equal 100 (Eurostat, 2016). Then three groups of countries have been identified according their GDP.

- Countries with GDP lower than 80 (-20% over the average EU28): Price elasticity = -0.5

- Countries with GDP between 80 and 120 (between ±20% of the average EU28): Price elasticity = -0.4

- Countries with GDP higher than 120 (+20% over the average EU28): Price elasticity = -0.3

Based on "Economic Analysis of Tobacco Demand – World Bank" (World Bank, 2016), four different models representing the evolution of consumption based on several independent variables such as price have been identified. Several articles ("Economics of tobacco: An analysis of cigarette demand in Ireland" (Statistics & Economic Research Branch, 2015), "New evidence on demand for cigarettes: a panel data approach" (Huang, Yang, & Hwang, 2004) and "Models of Irish tobacco consumption" (Conniffe, 1995)) claim that the function that better predicts the relation between consumption and price is a double-log function. Thus, it could be stated that:

$$\ln(Q_t) = b_0 + b_1 \cdot \ln(P_t) + f(other\ independent\ variables)$$

Where Q_t is the consumption for a specific time, P_t is the price, b_0 is a constant and b_1 is the price elasticity coefficient.

The consumption can be cleared up as:

$$Q_t = e^{b_0 + b_1 \cdot \ln(P_t) + f}$$

However, our interest relies in the variation in % of the consumption for the increment in price:

$$\Delta Q\% = \frac{Q_1 - Q_0}{Q_0} = \frac{e^{b_0 + b_1 \cdot \ln(P_1) + f} - e^{b_0 + b_1 \cdot \ln(P_0) + f}}{e^{b_0 + b_1 \cdot \ln(P_0) + f}} = e^{b_1 \cdot (\ln(P_1) - \ln(P_0))} - 1$$

$$\Delta Consumption\ (\%) = e^{Price\ Elasticity\ Coefficient \cdot \ln(\frac{Price_{Final}}{Price_{Initial}})} - 1$$

Data on illicit prices is not easy to acquire, as much of it is, by nature, unofficial. However, experts on the fight against illicit trade estimate that illicit tobacco products are sold at half the price of legal products (Joossens, Merriman, Ross, & Raw, 2010) (65% cheaper in Poland, 50% cheaper in UK, 40% cheaper in Romania). Then, for the purpose of this analysis the team has estimated an average price increase from illegal to legal tobacco products of 100% (buying in the legal market versus illicit market).

$$\Delta Q\% = e^{b_1 \cdot \ln\frac{P_1}{P_0}} - 1 = e^{PriceElasticityCoefficient \cdot \ln 2} - 1$$

Three ranges of price elasticity coefficients have been identified, which correspond to the following percentage of reduction in consumption:

Price elasticity coefficient	Reduction in tobacco consumption (%)
-0.3	18.77%
-0.4	24.21%
-0.5	29.29%

Table 12: Price elasticity

	GDP per capita in PPS (EU28 = 100)	Price elasticity (developed countries)	Percentage of consumers that would now decide to reduce their consumption or even quit smoking (%)	Percentage of consumers that would now purchase legitimate tobacco products (%)	Reduced consumption of tobacco products (Millions of unit packets)	New purchases of legitimate tobacco products (Millions of unit packets)
	(Q)	(R)	(S) =function of (R)	(T) = 100% - (S)	(U) = (N) · (S)	(V) = (N) · (T)
Austria	127	-0.3	18.77%	81.23%	6.37	27.56
Belgium	117	-0.4	24.21%	75.79%	2.77	8.66
Bulgaria	46	-0.5	29.29%	70.71%	3.91	9.44
Croatia	58	-0.5	29.29%	70.71%	1.83	4.42
Cyprus	81	-0.4	24.21%	75.79%	0.62	1.93
Czech Republic	87	-0.4	24.21%	75.79%	3.92	12.27
Denmark	123	-0.3	18.77%	81.23%	0.21	0.91
Estonia	74	-0.5	29.29%	70.71%	1.13	2.73
Finland	108	-0.4	24.21%	75.79%	1.27	3.96
France	105	-0.4	24.21%	75.79%	29.59	92.63
Germany	125	-0.3	18.77%	81.23%	17.98	77.77
Greece	70	-0.5	29.29%	70.71%	11.78	28.44
Hungary	68	-0.5	29.29%	70.71%	2.38	5.74
Ireland	172	-0.3	18.77%	81.23%	2.09	9.06
Italy	95	-0.4	24.21%	75.79%	11.52	36.07

Latvia	64	-0.5	29.29%	70.71%	1.98	4.77
Lithuania	73	-0.5	29.29%	70.71%	1.63	3.94
Luxembourg	270	-0.3	18.77%	81.23%	0.38	1.65
Malta	88	-0.4	24.21%	75.79%	0.16	0.49
Netherlands	128	-0.3	18.77%	81.23%	2.04	8.84
Poland	68	-0.5	29.29%	70.71%	15.51	37.46
Portugal	77	-0.5	29.29%	70.71%	2.95	7.13
Romania	57	-0.5	29.29%	70.71%	12.04	29.06
Slovakia	76	-0.5	29.29%	70.71%	1.22	2.94
Slovenia	82	-0.4	24.21%	75.79%	1.20	3.75
Spain	91	-0.4	24.21%	75.79%	13.19	41.29
Sweden	123	-0.3	18.77%	81.23%	1.75	7.56
United Kingdom	110	-0.4	24.21%	75.79%	12.61	39.48
Total	**100**	**-0.41**	**24.85%**	**75.15%**	**164.05**	**509.97**
Source: (Q): (Eurostat, 2016)						

Table 13: Estimated impact on illicit trade (II) – Detailed calculation

The conclusions of the analysis highlight that:

- 75.15% of illicit tobacco purchasers would now purchase legitimate tobacco products, increasing the legal tobacco sales by 509.97 million packs.
- 24.85% of illicit tobacco purchasers would now decide to reduce the consumption, or even quit smoking, leading to a reduction in tobacco consumption to the order of 164.05 million packs.

2.1.2. Assessment for the calculation of revenues by increase in sales

The following table represents the breakdown of revenues (VAT, excise duty, EO's revenue) by increase in sales.

	Price of a 20 cigarette pack of the most sold brand (€)	Average VAT (%)	Excise duties as % of the price	EO's revenue as % of the price	Impact on VAT (M€)	Impact on excise tax (M€)	Impact on EO's revenue tax (M€)
	(W)	(X)	(Y)	(Z) = 100% - (X) - (Y)	(A') = (V) · (W) · (X)	(B') = (V) · (W) · (Y)	(C') = (V) · (W) · (Z)
Austria	4.70 €	20.00%	57.79%	22.21%	25.91	74.86	28.77
Belgium	5.30 €	21.00%	56.53%	22.47%	9.63	25.94	10.31
Bulgaria	2.20 €	20.00%	64.20%	15.80%	4.16	13.34	3.28
Croatia	2.70 €	25.00%	53.09%	21.91%	2.98	6.34	2.62
Cyprus	4.50 €	19.00%	57.09%	23.91%	1.65	4.96	2.08
Czech Republic	2.70 €	21.00%	58.05%	20.95%	6.96	19.23	6.94
Denmark	5.80 €	25.00%	53.90%	21.10%	1.31	2.83	1.11
Estonia	2.60 €	20.00%	64.45%	15.55%	1.42	4.58	1.11
Finland	4.90 €	24.00%	61.98%	14.02%	4.66	12.04	2.72

France	6.60 €	20.00%	60.82%	19.18%	122.27	371.81	117.25
Germany	5.30 €	19.00%	55.44%	25.56%	78.32	228.52	105.36
Greece	3.80 €	24.00%	59.85%	16.15%	25.94	64.69	17.46
Hungary	2.60 €	27.00%	48.93%	24.07%	4.03	7.31	3.59
Ireland	9.40 €	23.00%	61.09%	15.91%	19.58	52.00	13.54
Italy	4.30 €	22.00%	54.73%	23.27%	34.12	84.88	36.09
Latvia	2.60 €	21.00%	60.26%	18.74%	2.60	7.47	2.32
Lithuania	2.20 €	21.00%	57.95%	21.05%	1.82	5.03	1.83
Luxembourg	4.40 €	17.00%	52.61%	30.39%	1.24	3.83	2.21
Malta	4.70 €	18.00%	62.92%	19.08%	0.42	1.45	0.44
Netherlands	6.00 €	21.00%	57.51%	21.49%	11.13	30.49	11.39
Poland	2.60 €	23.00%	58.21%	18.79%	22.40	56.69	18.30
Portugal	3.80 €	23.00%	55.05%	21.95%	6.23	14.92	5.95
Romania	3.10 €	20.00%	56.13%	23.87%	18.02	50.57	21.51
Slovakia	3.10 €	20.00%	59.30%	20.70%	1.83	5.41	1.89
Slovenia	3.10 €	22.00%	56.43%	21.57%	2.56	6.57	2.51
Spain	4.30 €	21.00%	57.82%	21.18%	37.29	102.66	37.60
Sweden	6.60 €	25.00%	49.05%	25.95%	12.47	24.46	12.94
United Kingdom	8.60 €	20.00%	63.99%	16.01%	67.90	217.26	54.36
Total	**4.38 €**	**21.50%**	**57.68%**	**20.82%**	**528.84**	**1,500.13**	**525.47**

Source:
(W): (Transcrime, Joint Reaseach Centre on Transational Crime, 2015)
(X): (European Comission - Taxation and Costumer Union, 2016)
(Y): (European Commision - Excise duty tables, 2016)

Table 14: Estimated impact on illicit trade (III) – Detailed calculation

Combining the 509.97 million packs that will now be bought on the legal market, and taking into account the price of tobacco packets and the tax levels in each country, the implementation of the solution is expected to generate:

- 528.84 million euros as new tax revenues from VAT;
- 1,500.13 million euros as new tax revenues from excise duties;
- 525.47 million euros as new revenues for the economic operators involved in the value chain of the tobacco products.

2.1.3. Assessment for the calculation of socio-economic benefits

In order to quantify these values, the Feasibility Study based itself on the TPD Impact Assessment (European Commission - TPD Impact Assessment, 2012) to analyse the monetary impact of decreased tobacco consumption, as presented below (in millions of euros). It shows the relation between the percentage reduction in tobacco consumption and the decrease in healthcare expenditure.

	Different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Decrease in health care expenditure	253	506	759	1,012	1,265
Increased productivity	83	165	248	331	413
All the values presented in million €					

Table 15: Different percentage reduction in tobacco consumption

As can be concluded from the previous table, there is a linear correlation between the percentage of reduction in tobacco consumption and the overall benefits for governments and society. The following equation shows the relation between them:

$$Decrease\ in\ healthcare\ expenditure\ (M€) = Coefficient_{Healthcare} \cdot \%Reduction\ in\ tobacco\ consumption$$

$$Increased\ productivity\ (M€) = Coefficient_{Productivity} \cdot \%Reduction\ in\ tobacco\ consumption$$

$$Coefficient_{Healthcare} = 25{,}300\ (D')$$

$$Coefficient_{Productivity} = 8{,}300\ (E')$$

According to the baseline values, the reduction of consumption, or even quitting smoking, is expected to generate:

- 154.03 million euros from reduction in healthcare expenditure;
- 50.53 million euros of increase in society productivity.

Estimated socio-economic benefits		
Health care expenditure coefficient	**(D')**	**25,300**
Increased productivity coefficient	**(E')**	**8,300**
Decrease in health care expenditure (M€)	**(F') = (D') · (S) · (P)**	**154.03**
Increased productivity (M€)	**(G') = (E') · (S) · (P)**	**50.53**
Source: (D') (E'): (European Commission - TPD Inception Impact Assessment, 2016)		

Table 16: Estimated socio-economic benefits

2.1.4. Assessment for the calculation of social and environmental benefits

It is also possible to quantify the reduction in tobacco products consumption in terms of people. For this calculation, the number of population over 15 years old in the 28 Member States was considered (Eurostat, 2015) (429.1 million people) and the current smoking rate of tobacco consumers.

As a result, when considering the overall reduction in illicit trade (2.45%) and the percentage of consumers that would now decide to reduce their consumption or even quit smoking (24.85%), the number of people that will reduce consumption of quit smoking stands at 0.712 million people.

Total population (Millions of people)	Population above 15 years old (Millions of	Current smoking rate of tobacco (%)	Number of people who will reduce or quit

		people)		smoking (Millions of people)
	(H')	(I')	(J')	(K') = (P) · (S) · (I') · (J')
Austria	8.58	7.35	28%	0.016
Belgium	11.26	9.34	19%	0.009
Bulgaria	7.20	6.20	36%	0.014
Croatia	4.23	3.60	35%	0.007
Cyprus	0.85	0.71	28%	0.002
Czech Republic	10.54	8.94	29%	0.010
Denmark	5.66	4.70	19%	0.001
Estonia	1.31	1.10	23%	0.003
Finland	5.47	4.58	20%	0.005
France	66.42	54.06	36%	0.212
Germany	81.20	70.51	25%	0.073
Greece	10.86	9.28	37%	0.038
Hungary	9.86	8.43	27%	0.012
Ireland	4.63	3.60	19%	0.007
Italy	60.80	52.41	24%	0.038
Latvia	1.99	1.69	32%	0.008
Lithuania	2.92	2.50	29%	0.006
Luxembourg	0.56	0.47	21%	0.001
Malta	0.43	0.37	24%	0.000
Netherlands	16.90	14.07	19%	0.009
Poland	38.01	32.29	30%	0.062
Portugal	10.37	8.88	26%	0.015
Romania	19.87	16.79	28%	0.046
Slovakia	5.42	4.59	26%	0.004
Slovenia	2.06	1.76	28%	0.003
Spain	46.45	39.40	28%	0.053
Sweden	9.75	8.07	7%	0.003
United Kingdom	64.88	53.41	17%	0.057
Total	**508.45**	**429.11**	**25.71%**	**0.712**

Source:
(H') (I'): (Eurostat, 2015)
(J'): (Eurobarometer, 2017)

Table 17: Assessment for the calculation of the social and environmental benefits (I)

The TPD Impact Assessment (European Commission - TPD Impact Assessment, 2012) estimates the value of one life year at €52,000. The total number of life years lost per country (DG SANCO, 2008) is reviewed in order to estimate the monetary value of life years saved by the effective implementation of the proposed measures. The following table estimates these values for EU28.

Total YLL due to smoking	Reduction in YLL by the effective implementation of the proposed measures	Monetary value of loss (M€)

	(L')	(M') = (L') · (P) · (S)	(N') = (M') · 52,000€
Austria	132,411	1,044	54.31
Belgium	226,637	1,103	57.33
Bulgaria	179,103	1,153	59.94
Croatia			
Cyprus			
Czech Republic	219,861	818	42.53
Denmark	157,613	115	6.00
Estonia	25,989	256	13.32
Finland	65,266	361	18.75
France	1,116,577	12,152	631.90
Germany	1,563,453	6,449	335.35
Greece	206,717	2,268	117.96
Hungary	434,458	2,383	123.91
Ireland	67,451	717	37.28
Italy	992,332	3,002	156.10
Latvia	48,974	695	36.12
Lithuania	66,660	563	29.28
Luxembourg	5,582	30	1.54
Malta	4,900	25	1.30
Netherlands	365,121	1,297	67.45
Poland	1,080,437	6,917	359.69
Portugal	130,191	858	44.63
Romania	511,757	4,985	259.20
Slovakia	98,134	314	16.34
Slovenia	37,966	217	11.31
Spain	721,281	3,452	179.48
Sweden	122,421	638	33.16
United Kingdom	1,355,499	8,463	440.07
Total	**9,936,791**	**60,274**	**3,134**

Source:
(L'): (DG SANCO, 2008)
Missing values for Croatia and Cyprus

Table 18: Assessment for the calculation of the social and environmental benefits (II)

2.2. Detailed calculation of the costs

In order to support the evaluation of the policy options performed in Interim Report II, we have analysed the cost of each of the options proposed for each of the decision points.

The cost analysis differentiates between economic stakeholders and competent authorities. Also, the costs have been taken into account according to the economic stakeholder that incurs the cost, independently of who is held ultimately responsible of the cost. For example, Article 15.7 of the TPD states that the manufacturers shall provide all economic operators with the equipment that is needed for the recording of

movements of tobacco products. The cost of this equipment is calculated for each of the economic operators (and not for the manufacturers, who are held responsible of these costs according to the TPD).

2.2.1. Common parameters and general assumptions

In order to analyse the costs of the entire new Tracking and Tracing System in the tobacco supply chain and to analyse the burden for the different parties of the different alternatives in the proposed policy options, we have sliced the total cost into five different parts corresponding with the five proposed policy options, as explained below:

For option A (Governance model), which ensures the required level of system integrity by the allocation of various responsibilities and functions to the operators involved in the supply chain, several costs are identified: the serial number generation, Data Carrier Printing, uTrack kit implementation, control and auditing of the Tracking and Tracing System.

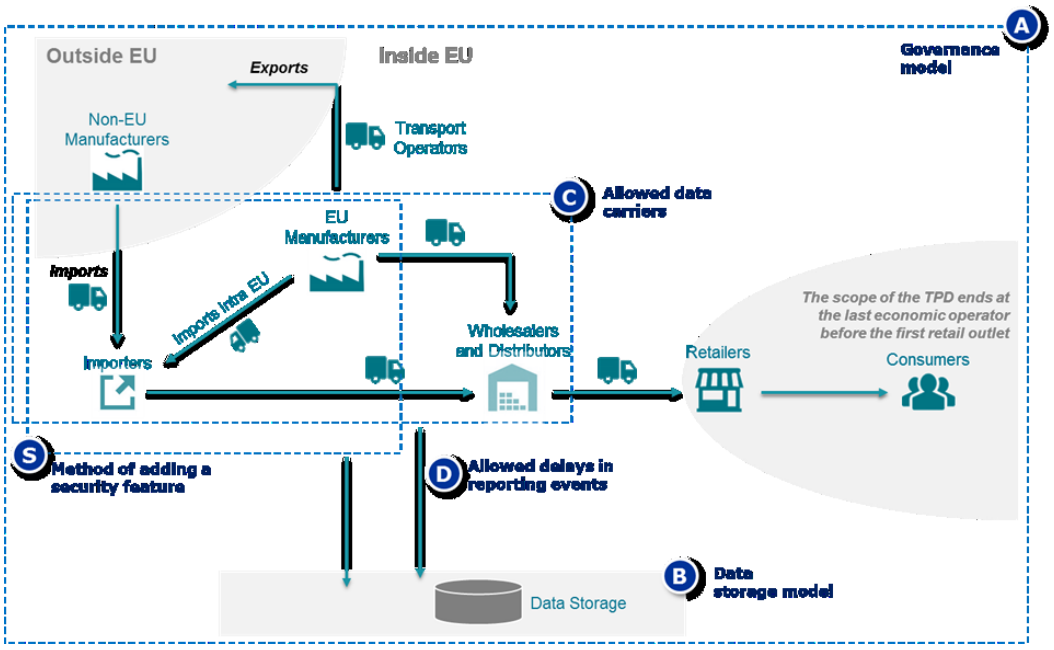
For option B (Data storage model), the aim of the data storage is to store all relevant data reported by the economic operators, assure its integrity, and make it accessible to the competent authorities for surveillance purposes. Identified costs are related with software, hardware, communications and system auditing.

Option C (Allowed data carriers) aims at describing the allowed set of data carriers that will contain the unique identifier. Identified costs are related with uTrack kit implementation, data carrier printing and registration costs.

Option D presents the choice of allowed delays in reporting events, which ensures that traceability and trade data are transmitted and recorded into the Tracking and Tracing System. Identified costs are related with software and hardware integration.

Option S (Method of adding a security feature) focuses on how to add the security features to unit packets of tobacco products. Identified costs are related with how to add the security features to unit packets of tobacco products

For this analysis, all the decision points were verified and the sum of the decisions taken will compose the high level system shown below.



Type of Tobacco Products

The costs are analysed considering the impact on all type of tobacco products:

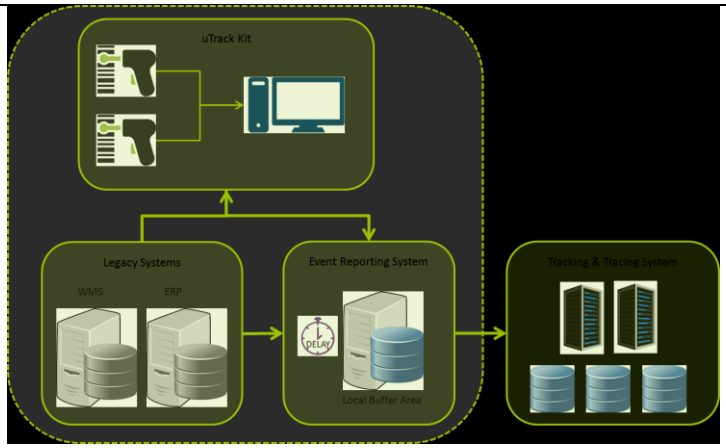
- Cigarette packs
- RYO
- Cigars
- Pipe tobacco
- Smokeless tobacco – chewing/ snus

Financial Assumptions:

Financial Figures	Value	Source
Depreciation of all capital expenses	6 years	Feasibility Study (European Commission - Feasibility Study, 2015, p. 295)
Annual maintenance costs (HW or SW)	10% of CAPEX	Feasibility Study (European Commission - Feasibility Study, 2015, p. 300)
Commercial margin for the Independent Third Party	10%	Feasibility Study (European Commission - Feasibility Study, 2015, p. 301)

uTrack kit description:

The uTrack kit is a software and hardware equipment responsible for reading the data carriers.

uTrack kit description	
Composition	(1) The uTrack kit is composed of two handheld scanners and a computer. ()* The uTrack kit is proposed as the minimum necessary equipment to scan the data carriers, read and record the unique identifier and upload the data to the track and trace system.
Use case	(2) Shipment's reception of tobacco products in a warehouse 1. The handheld scanner reads the data carrier issued in each pallet. 2. The uTrack kit computer detects the list of unique identifiers contained in the data carriers. 3. The uTrack kit computer sends the list of unique identifiers to the event reporting system, as well as the legacy system. 4. The event reporting system compliments the read unique identifiers to generate the event reporting messages. 5. The event reporting system reports the events to the tracking and tracing data system.
Description	

Disaggregation and Re-aggregation

Currently, the operators of the distribution chain deal with disaggregation and re-aggregation at different aggregation packaging levels in order to optimise their reporting activities. In this regard, it is estimated that the following average of re-aggregation activities will take place in the big distributors' facilities:

Re-aggregation

Figures	Value[14]	Source
Mastercase distribution	25%	Team Operational experience
Pallet distribution	50%	Team Operational experience

[14] The team has estimated this percentage of re-aggregation on basis of the type of aggregation packaging levels and the characteristics of the distribution chain of tobacco products

It is estimated that the disaggregation activities take place gradually in all the economic operators of the distribution chain, concluding:

Disaggregation

Figures	Value[15]	Source
Pallet to mastercase	100%	Team Operational experience
Mastercase to carton	50%	Team Operational experience

Anti-tampering equipment

It is estimated that the cost for adapting the standard tracking and tracing equipment to be anti-tampering is the following:

Figures	Value	Source
Cost of transforming standard equipment into anti-tampering equipment (including both mechanical and/or digital solutions)	10%	Team Operational experience
Technical support from independent third parties to remove, repair, check and/or replace the anti-tampering solutions (The cost of the anti-tampering consumables is considered negligible) Frequency: once a year, every manufacturing facility will require technical support in some of its production lines. This support is estimated to 0.5 days (Team estimation)	666.67 €	The cost is considered to be equivalent to an auditor; based on (European Commission - Impact Assessment FMD, 2008, p. 81). The unitary cost of these audits is 4,000 € for 3 days.

2.2.1.1. Volumes

Annual Consumption

Figures	Value	Source
Cigarettes - Unit packets	24,395,800,000	Inception Impact Assessment (European Commission - TPD Inception Impact Assessment, 2016)
RYO unit packets	1,000,000,000	Feasibility Study (European Commission - Feasibility Study, 2015, p. 323)
Cigars (boxes) - Unit packets	959,000,000	Feasibility Study (European Commission - Feasibility Study, 2015, p. 323)
Pipe tobacco - Unit packets	80,000,000	Feasibility Study (European Commission - Feasibility Study, 2015, p. 323)
Smokeless tobacco (chewing) - Unit packets	1,800,000	Feasibility Study (European Commission - Feasibility Study, 2015, p. 323)
Exports	3,204,800,000	

[15] The team has estimated this percentage of re-aggregation on basis of the type of aggregation packaging levels and the characteristics of the distribution chain of tobacco products

TOTAL UNIT PACKETS	29,641,400,000	
Packs in a carton	10	
Cartons in a mastercase	50	
Mastercases in a pallet	50	
Cartons	2,964,140,000	
Mastercases	59,282,800	
Pallets	1,185,656	
TOTAL AGGREGATION LEVELS	3,024,608,456	
TOTAL LABELS	32,666,008,456	

NOTE - Exports (Calculation method)

Disclaimer

This study aims to present the calculations for the estimation of the total unit packets that are exported outside EU28. The baseline for this calculation are the EU Trade data sets Eurostat (Eurostat, 2015) for the exports of the products 2402 (Cigars, Cheroots, Cigarillos & Cigarettes of tobacco and tobacco substitutes) and 2403 (Manufactured tobacco & manufactured tobacco substitutes and "Homogenized" or "Reconstituted" tobacco, tobacco extracts and tobacco essences.

In order to calculate the number of unit packets exported outside EU28 the following assumptions have been made:

1. All the products of the groups 2402 and 2403 should be marked with the UID.
2. The team estimates that the average price of the unit packet for all tobacco products is similar to the price of a 20 cigarettes unit packet.

Besides, to calculate the number of unit packets exported the price of the unit packet (taxes excluded) is used. The following table exhibits the values for the exports outside EU28 for each Member State.

	Exports outside EU28 for products 2402 & 2403 (millions of Euros)	Average price per 20 cigarette pack	% of product price without taxes	Average price per 20 cigarette pack (Tax excluded)	Exports outside EU28 for products 2402 & 2403 (millions of unit packets)
	(A)	(B)	(C)	(D) = (B) * (C)	(E) = (A) / (D)
Austria	0.57	4.48 €	22.21%	1.00 €	0.58
Belgium	75.03	5.51 €	22.47%	1.24 €	60.60
Bulgaria	198.78	2.42 €	15.80%	0.38 €	519.86
Croatia	26.69	3.00 €	21.91%	0.66 €	40.60
Cyprus	2.55	4.21 €	23.91%	1.01 €	2.53
Czech Republic	56.45	2.95 €	20.95%	0.62 €	91.34
Denmark	71.62	5.47 €	21.10%	1.15 €	62.05
Estonia	0.37	3.07 €	15.55%	0.48 €	0.78
Finland	3.28	5.67 €	14.02%	0.79 €	4.13
France	120.81	6.75 €	19.18%	1.29 €	93.32

Germany	1,443.43	5.34 €	25.56%	1.36 €	1,057.53
Greece	161.25	3.71 €	16.15%	0.60 €	269.12
Hungary	5.47	3.38 €	24.07%	0.81 €	6.72
Ireland	1.96	9.68 €	15.91%	1.54 €	1.28
Italy	15.18	4.66 €	23.27%	1.08 €	14.00
Latvia	2.19	2.89 €	18.74%	0.54 €	4.04
Lithuania	55.01	2.77 €	21.05%	0.58 €	94.34
Luxembourg	21.99	4.50 €	30.39%	1.37 €	16.08
Malta	0.02	4.92 €	19.08%	0.94 €	0.03
Netherlands	329.28	6.05 €	21.49%	1.30 €	253.27
Poland	124.40	3.13 €	18.79%	0.59 €	211.52
Portugal	61.01	4.29 €	21.95%	0.94 €	64.79
Romania	43.56	3.28 €	23.87%	0.78 €	55.63
Slovakia	0.17	3.51 €	21.57%	0.76 €	0.22
Slovenia	0.25	3.06 €	20.70%	0.63 €	0.39
Spain	64.11	4.44 €	21.18%	0.94 €	68.18
Sweden	186.03	5.59 €	21.78%	1.22 €	152.80
United Kingdom	99.90	10.49 €	16.01%	1.68 €	59.48
Total	**3,171.35**	**4.62 €**	**20.67%**	**0.95 €**	**3,204.80**

Source:
(B) (Centre on Transational Crime, 2015)
(C) (European Comission - Taxation and Costumer Union, 2016)

Installed Base

- Manufacturing Facilities - The Feasibility Study (European Commission - Feasibility Study, 2015, p. 297) assumed that 40% of the manufacturing facilities were 'big' and they will need up to four UTrack kit packs. Other 60% will require only two kits per facility
- Wholesalers & Big Distributors Entities – Feasibility Study (European Commission - Feasibility Study, 2015, p. 305) used available data from Eurostat, which showed that the number of wholesale companies operating in the tobacco market in the EU was 2450 in 2012.
- Warehousing Facilities – Regarding the 'big facilities', there is not a clear definition. The Feasibility Study classifies facilities as follows:

  - Big facilities: those warehouse facilities that require being equipped with thee uTrack kits.

  - Other facilities: those warehouse facilities that require being equipped with one uTrack kit.

  - The Feasibility Study (European Commission - Feasibility Study, 2015, p. 308) estimates 30% big facilities – 70% medium/small warehouse facilities

Figures	Value	Source
Manufacturing facilities	332	Feasibility Study (European Commission - Feasibility Study, 2015, p. 296)
Big manufacturing facilities	133	Feasibility Study (European Commission - Feasibility Study, 2015, p. 297)

Small medium manufacturing facilities	199	Feasibility Study (European Commission - Feasibility Study, 2015, p. 297)
Production lines	743	Feasibility Study (European Commission - Feasibility Study, 2015, p. 324)
High speed production lines	46	Feasibility Study (European Commission - Feasibility Study, 2015, p. 293)
Low medium speed production lines	697	Feasibility Study (European Commission - Feasibility Study, 2015, p. 293)

Figures	Value	Source
Big distributors & wholesalers	2450	Feasibility Study (European Commission - Feasibility Study, 2015, p. 378)
Warehousing facilities	7690	Feasibility Study (European Commission - Feasibility Study, 2015, p. 279)
Big warehousing facilities	2307	Feasibility Study (European Commission - Feasibility Study, 2015, p. 279)
Small and medium warehouses	5383	Feasibility Study (European Commission - Feasibility Study, 2015, p. 279)
Vending machine service vans	1944	Feasibility Study (European Commission - Feasibility Study, 2015, p. 380)
Mobile sales force units	3669	Feasibility Study (European Commission - Feasibility Study, 2015, p. 311)

2.2.1.2. Unitary costs

Manufactures & Importers – CAPEX Data

Concept	Type	Minimum	Maximum	Selected Value	Source
Pack printer and verification equipment (including Installation)	HS Prod Lines	290,000€	355,000€	322,500€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
Pack printer and verification equipment (including Installation)	LS Prod Lines	30,000€	57,000€	43,500€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
Cost of carton printer and verification equipment (including Installation)	HS Prod Lines	112,166€	112,166€	112,166€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
Cost of carton printer and verification equipment (including Installation)	LS Prod Lines	6,000€	13,000€	9,500€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
Cost of mastercase printer and verification equipment (including Installation)	HS Prod Lines	11,340€	11,340€	11,340€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)

Cost of mastercase printer and verification equipment (including Installation)	LS Prod Lines	4,750€	4,750€	4,750€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
Cost of pallet printer and verification equipment (including Installation)	All manufacturing facilities	3,000€	3,000€	3,000€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)

Manufacturing– OPEX Data

Concept	Type	Minimum	Maximum	Selected Value	Source
Operational cost - Unit packet (related to unit packet printing)	All manufacturing facilities	0.00015 €	0.00006 €	0.000375 €	Industry survey of the Feasibility Study
Operational cost - Carton, mastercase, pallet (related to carton, MC, pallet)	All manufacturing facilities	0.0021 €	0.0021 €	0.0021 €	Feasibility Study (European Commission - Feasibility Study, 2015, p. 295)

Distribution – CAPEX Data

Concept	Type	Minimum	Maximum	Selected Value	Source
Mastercase and pallet label printing	Big facilities	3,000€	3,000€	3,000€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)
uTrack kit (Software equipment responsible for reading the data carriers and delivering the information to the legacy system)	Wholesalers and Distributors, Vans and Mobile Forces	10,000€	10,000€	10,000€	Feasibility Study (European Commission - Feasibility Study, 2015, p. 294)

2.2.1.3. Scope of policy options

To support the evaluation performed in Chapter 4 of Interim Report II, the cost of each of the options proposed for each of the decision points was analysed.

The cost analysis differentiates between economic stakeholders and competent authorities, and also between types of costs (CAPEX - capital expenditure, funds used by a company to acquire or upgrade physical assets; OPEX - operational expenditure is the money a company spends on a day-to-day basis in order to run a business or system).

Policy options type of costs

Policy Option	Cost	Stakeholder	Comments	Type of Cost	Comments
Governance Model	UID: Generation	Manufacturers and importer	For all unit packets and all aggregation packaging levels	OPEX	·Third party generation. No Equipment CAPEX required
		Big distributors	Only for re-aggregations.		
	Data Carrier: - Printing / Affixing, - Verification	Manufacturers and importers	For all unit packets and all aggregation packaging levels	CAPEX and OPEX	·Printing and verification equipment
		Big distributors	Only for re-aggregations.	CAPEX and OPEX	·Printing and verification equipment
	Data Carrier: - Scanning	Manufacturers, Importers,	Scanning activities for reporting events	CAPEX and OPEX	·uTrack kit ·Company Server and Software
	Control the tracking and tracing system	Competent authorities	Physical presence of law enforcement agents	OPEX	
	Audit of the system and the activities of the 3rd party	Competent authorities and External Auditors	Regular and random audits.	OPEX	
Data storage models	T&T System: Software and Hardware	Manufacturers, and Importers	All components	CAPEX and OPEX	
	Communications between facilities		infrastructure between systems	OPEX	
	Third party data storage auditing	Competent authorities	Auditing of the third party data storage provider activities	OPEX	
Allowed data carriers	Data Carrier: - Printing / Affixing, - Verification	Manufacturers and importers	Incremental differences from the Governance model	CAPEX and OPEX	Printing and verification equipment
		Big distributors	Incremental differences from the Governance model	CAPEX and OPEX	·Printing and verification equipment
	Data Carrier: - Scanning	Wholesalers, Distributors, Service Vans and Mobile sales forces	Scanning activities for reporting events	CAPEX and OPEX	·uTrack kit ·Company Server and Software
Allowed reporting delays	Software and Hardware per facility	Manufacturers, Importers, Wholesalers, Distributors, Service Vans and Mobile sales forces	Reporting events system	CAPEX and OPEX	
Method of adding a security feature	Printing or Affixing at unit packet level	Competent authorities, manufactures and importers		OPEX	

All of these costs are related to one (or more) set of core activities, including:

- Generating UID
- Printing / affixing
- Scanning / verifying
- Auditing / controlling
- Reporting

Each set of activities includes:

- Capital costs (equipment and infrastructures, including installation).
- Operational costs (repair and maintenance, supplies, office and facility expenses, salaries and wages and llicences and registration).

2.2.2. Governance model

2.2.2.1. Baseline and scope

The scope of this policy option is the allocation to the economic operators involved in the supply chain of tobacco products of the following functionalities of the system:

- Generation of the unique identifier for unit packets and the different aggregation levels.
- Printing or affixing the unique identifier into each unit packet and the different aggregation levels.
- Scanning / verification of the unique identifiers applied into the tobacco products (unit packets and aggregation levels).
- Ensure general control of the system.
- Perform the necessary audits to the system.

The baseline for this policy option is the tracking and tracing solution being developed by some of the members of the industry. This solution's reuse of pieces of equipment in the new tracking and tracing system implemented as a result of the TPD has not been considered for the cost analysis of the options for a governance model, mainly because:

(a) The compliance of the solution developed by the industry with the TPD and the FCTC protocol has triggered vigorous discussion; and

(b) The opacity of these proprietary solutions does not contribute to the analysis of potential reuses.

However, the potential synergies between the current equipment and the new Tracking and Tracing System are taken into consideration when analysing the costs for 'Allowed data carriers'.

In the analysis of the costs of options for a governance model, the costs of marking tobacco products other than cigarettes and roll-your-own tobacco have been taken into consideration.

2.2.2.2. Assumptions

In the following table, the main assumptions for the governance model are summarised, comparing between the current situation and the implications of the different options:

	Current situation	Option A1	Option A2	Option A3
Generation of the UID	Some members of the industry have developed their own solution for tracking and tracing of tobacco products. The degree of reuse of pieces of equipment in the new tracking and tracing system is uncertain.	Codes generated by manufacturers and importers for unit packets and aggregation levels, and by big distributors for re-aggregations.	Codes generated by an independent third party.	Codes generated by an independent third party or by the competent authorities in cooperation with an independent third party.
Printing / Affixing		Printing/affixing done by manufacturers and importers. **Assumption:** • Printing the unique identifiers for unit packets (high speed). • Affixing (labelling) the unique identifiers for aggregation levels. Printing/affixing done by big distributors for re-aggregation levels.	Printing/affixing done by an independent third party. **Assumption:** A profit component for the independent third party is estimated, added to the cost calculated in A1.	Printing/affixing done by manufacturers and importers. **Assumption:** • Printing the unique identifiers for unit packets (high speed). • Affixing (labelling) the unique identifiers for aggregation levels. Printing/affixing done by big distributors for re-aggregation levels.
Scanning / Verification		Scanning/ verification done by the industry (and the distributors for the unique identifiers applied as a result of the re-aggregation process).	Scanning/ verification done by independent third party. **Assumption:** A profit component for the independent third party is estimated, added to the cost calculated in A1.	Scanning/ verification done by the industry, with anti-tampering devices owned by a third party. **Assumption:** An additional cost of 10% is estimated for transforming standard equipment into anti-tampering equipment (including both mechanical and/or digital solutions). Technical support is foreseen to remove, repair, check and/or replace the anti-tampering solutions (666.67 €/year/production line).
General control of the system	There are no controls implemented to monitor the traceability of tobacco products.	Extensive controls of the system by the competent authority required. **Assumption:** • 1 FTE can control 1 high speed production line. • 0.5 FTE can control 1 low/medium speed line.	The control of the system is ensured through the presence of an independent third party in all the processes.	The control of the system is ensured through the presence of independent third parties (or competent authorities) in key processes of the system that allow reconciliation of number of units of tobacco product to be marked.
Auditing of the system	Only for fiscal purposes and reconciliation (tax and	Regular and random audits.	Regular and random audits.	Regular and random audits (higher frequency). **Assumption:**

	customs authorities).			• Coefficient for higher frequency: 1.5
Auditing the activities of the third party	-	-	External auditor monitoring the activities of the third party. **Assumption:** • 50% additional auditing costs.	External auditor monitoring the activities of the third party. **Assumption:** • 30% additional auditing costs (the third party is responsible for functions in A3).

2.2.2.3. Figures, volumes and unitary costs

The following tables present the unitary costs (those not presented in sub-section Common parameters and general assumptions) divided by type of economic operator (manufacturer & importer and distribution chain operators) and by type of cost (CAPEX, OPEX).

Concept	Type	Minimum	Maximum	Selected Value	Source
Serial number generation	Per serial number generation	0.000229 €	0.000628 €	0.000429 €	Industry survey of the Feasibility Study

Manufacturers & Importers – CAPEX

Concept	Type	Minimum	Maximum	Selected Value	Source
Installation local support (not included above)	High speed production lines	-	-	15,000€	Feasibility Study
Installation local support (not included above)	Low-medium speed production lines	-	-	10,000€	Feasibility Study

Wholesalers & Big Distributors – CAPEX

Concept	Type	Minimum	Maximum	Selected value	Source
Company server and software	All warehousing facilities	-	-	6,000€	Feasibility Study

Independent Third Parties

Concept	Type	Value	Source
Commercial margin for the independent third party	Activities of the third party	10% commercial margin	Feasibility Study

Competent authorities

Concept	Type	Value	Source
EU-28 Labour cost for employee of public administration	FTE/year	36,912.00 €	(Eurostat, 2013)

External Auditors

Concept	Type	Value	Source
Cost for purchasing a third party audit	All manufacturing facilities	4,000.00 €	(European Commission - Impact Assessment FMD, 2008, p. 81)

2.2.2.4. Results

2.2.2.4.1. Generation of the unique identifier

Manufacturers & Importers – OPEX

Cost Description	Number of codes	A1	A2	A3
Serial number generation	32,666,008,456	14,007,941 €	- €	- €

Manufacturers & Importers – TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	14,007,941 €	- €	- €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	14,007,941 €	- €	- €

Wholesalers and Big Distributors – OPEX

Cost Description	Number of codes	A1	A2	A3
Serial number generation	15,413,528	6,610 €	- €	- €

Wholesalers and Big Distributors - TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	6,610 €	- €	- €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	6,610 €	- €	- €

Independent Third Parties – OPEX

Cost Description	Number of codes	A1	A2	A3
Serial number generation	32,681,421,984	- €	14,014,551 €	14,014,551 €

Independent Third Parties - TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	- €	14,014,551 €	14,014,551 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	- €	14,014,551 €	14,014,551 €

2.2.2.4.2. Printing or affixing the unique identifier and verification of the data carriers applied

Manufacturers & Importers – CAPEX

Cost Description	A1	A2	A3
Pack printer and verification equipment (including Installation) in high speed production lines	14,835,000 €	- €	16,318,500 €
Pack printer and verification equipment (including Installation) in low/medium speed production lines	30,319,500 €	- €	33,351,450 €
Carton printer and verification equipment (including Installation) in high speed production lines	5,159,636 €	- €	5,675,599 €
Carton printer and verification equipment (including Installation) in low/medium speed production lines	6,621,500 €	- €	7,283,650 €
Mastercase printer and verification equipment (including Installation) in high speed production lines	521,640 €	- €	573,804 €
Mastercase printer and verification equipment (including Installation) in low/medium speed production lines	3,310,750 €	- €	3,641,825 €
Pallet printer and verification equipment (including Installation) in big manufacturing facilities	399,000 €	- €	438,900 €
Pallet printer and verification equipment (including Installation) in small/medium manufacturing facilities	597,000 €	- €	656,700 €
Installation local support (not included above) in high speed production lines	690,000 €	- €	690,000 €
Installation local support (not included above) in low/medium speed production lines	6,970,000 €	- €	6,970,000 €
TOTAL	**69,424,026 €**	**- €**	**75,600,429 €**

Manufacturers & Importers – OPEX

Cost Description	A1	A2	A3
Technical support from independent third parties to remove, repair, check and/or replace the tamper-evident solutions	- €	- €	221,333 €
Marking each unit packet	1,778,484 €	- €	1,778,484 €
Marking each carton	6,224,694 €	- €	6,224,694 €
Marking each mastercase	124,494 €	- €	124,494 €
Marking each pallet	2,490 €	- €	2,490 €

Factory software and maintenance (10%)	766,000 €	- €	766,000 €
TOTAL	**8,896,162 €**	**- €**	**9,117,495 €**

Manufacturers & Importers – TOTAL

	A1	A2	A3
CAPEX	69,424,026 €	- €	75,600,429 €
OPEX	8,896,162 €	- €	9,117,495 €
Annual depreciation	11,570,671 €	- €	12,600,071 €
Annualised total costs (OPEX + depreciation)	**20,466,833 €**	**- €**	**21,717,567 €**

Wholesalers and Big Distributors - CAPEX

Cost Description	A1	A2	A3
Mastercase and pallet label printing equipment for distributors and wholesalers in big warehousing facilities	6,921,000 €	- €	6,921,000 €
Company server and software installation in each big warehousing facility	13,842,000 €	- €	13,842,000 €
TOTAL	**20,763,000 €**	**- €**	**20,763,000 €**

Wholesalers and Big Distributors - OPEX

Cost Description	A1	A2	A3
Company server and software maintenance (10%)	1,384,200 €	- €	1,384,200 €
Cost of re-labelling every mastercase (25% of total volume)	31,123 €	- €	31,123 €
Cost of re-labelling every pallet (50% of total volume)	1,245 €	- €	1,245 €
TOTAL	**1,416,568 €**	**- €**	**1,416,568 €**

Wholesalers and Big Distributors - TOTAL

	A1	A2	A3
CAPEX	20,763,000 €	- €	20,763,000 €
OPEX	1,416,568 €	- €	1,416,568 €
Annual depreciation	3,460,500 €	- €	3,460,500 €
Annualised total costs (OPEX + depreciation)	**4,877,068.41 €**	**- €**	**4,877,068.41 €**

Independent Third Parties - CAPEX

	Cost Description	A1	A2	A3
MANUFACTURERS & IMPORTERS	Pack printer and verification equipment (including Installation) in high speed production lines	- €	16,318,500 €	- €
	Pack printer and verification equipment (including Installation) in low/medium speed production lines	- €	33,351,450 €	- €
	Carton printer and verification equipment (including Installation) in high speed production lines	- €	5,675,599 €	- €

	Carton printer and verification equipment (including Installation) in low/medium speed production lines	- €	7,283,650 €	- €
	Mastercase printer and verification equipment (including Installation) in high speed production lines	- €	573,804 €	- €
	Mastercase printer and verification equipment (including Installation) in low/medium speed production lines	- €	3,641,825 €	- €
	Pallet printer and verification equipment (including Installation) in big manufacturing facilities	- €	438,900 €	- €
	Pallet printer and verification equipment (including Installation) in small/medium manufacturing facilities	- €	656,700 €	- €
	Installation local support (not included above) in high speed production lines	- €	759,000 €	- €
	Installation local support (not included above) in low/medium speed production lines	- €	7,667,000 €	- €
BIG DISTRIBUTORS &	Mastercase and pallet label printing equipment for distributors and wholesalers in big warehousing facilities	- €	7,613,100 €	- €
	Company server and software installation in each big warehousing facility	- €	16,170,000 €	- €
TOTAL		**- €**	**100,149,528 €**	**- €**

Independent Third Parties - OPEX

	Cost Description	A1	A2	A3
MANUFACTURERS &	Marking each unit packet	- €	1,956,332 €	- €
	Marking each carton	- €	6,847,163 €	- €
	Marking each mastercase	- €	136,943 €	- €
	Marking each pallet	- €	2,739 €	- €
	Factory software and maintenance (10%)	- €	842,600 €	- €
BIG DISTRIBUT	Company server and software maintenance (10%)	- €	1,617,000 €	- €
	Cost of re-labelling every mastercase (25% of total volume)	- €	34,236 €	- €
	Cost of re-labelling every pallet (50% of total volume)	- €	1,369 €	- €
TOTAL		- €	**11,438,383 €**	- €

Independent Third Parties - TOTAL

	A1	A2	A3
CAPEX	- €	100,149,529 €	- €
OPEX	- €	11,438,383 €	- €
Annual depreciation	- €	16,691,588 €	- €
Annualised total costs (OPEX + depreciation)	- €	28,129,971 €	- €

2.2.2.4.3. Permanent control of the system

Competent authorities - OPEX

Cost Description	A1	A2	A3
Presence of law enforcement agents in high speed production lines (1 FTE / prod. line)	1,697,952 €	- €	- €
Presence of law enforcement agents in medium and low speed production lines (0.5 FTE / prod. line)	12,863,832 €	- €	- €
TOTAL	14,561,784 €	- €	- €

Competent authorities - TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	14,561,784 €	- €	- €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	14,561,784 €	- €	- €

2.2.2.4.4. Audits of the system

Competent authorities - OPEX

Cost Description	A1	A2	A3
Auditing manufacturers facilities	1,328,000 €	1,328,000 €	1,992,000 €
TOTAL	**1,328,000 €**	**1,328,000 €**	**1,992,000 €**

Competent authorities - TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	1,328,000 €	1,328,000 €	1,992,000 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	- €	- €	- €

External Auditors - OPEX

Cost Description	A1	A2	A3
Auditing the activities of the independent third party	- €	664,000 €	398,400 €
TOTAL	**- €**	**664,000 €**	**398,400 €**

External Auditors - TOTAL

	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	- €	664,000 €	398,400 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	- €	664,000 €	398,400 €

2.2.2.5. Summary

TOTAL	A1	A2	A3
CAPEX	90,187,026 €	100,149,529 €	96,363,429 €
OPEX	40,217,065 €	27,444,934 €	26,939,014 €
Annual depreciation	15,031,171 €	16,691,588 €	16,060,571 €
Annualised total costs (OPEX + depreciation)	55,248,236 €	44,136,522 €	42,999,585 €
Total annualised cost per unit marked	**0.0019 €**	**0.0015 €**	**0.0015 €**

MANUFACTURERS & IMPORTERS	A1	A2	A3
CAPEX	69,424,026 €	- €	75,600,429 €
OPEX	22,904,103 €	- €	9,117,495 €
Annual depreciation	11,570,671 €	- €	12,600,071 €
Annualised total costs (OPEX + depreciation)	34,474,774 €	- €	21,717,567 €

WHOLESALES & BIG DISTRIBUTORS	A1	A2	A3
CAPEX	20,763,000 €	- €	20,763,000 €
OPEX	1,423,178 €	- €	1,416,568 €
Annual depreciation	3,460,500 €	- €	3,460,500 €
Annualised total costs (OPEX + depreciation)	4,883,678 €	- €	4,877,068 €

INDEPENDENT THIRD PARTIES	A1	A2	A3
CAPEX	- €	100,149,529 €	- €
OPEX	- €	25,452,934 €	14,014,551 €
Annual depreciation	- €	16,691,588 €	- €
Annualised total costs (OPEX + depreciation)	- €	42,144,522 €	14,014,551 €

COMPETENT AUTHORITIES	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	15,889,784 €	1,328,000 €	1,992,000 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	15,889,784 €	1,328,000 €	1,992,000 €

EXTERNAL AUDITORS	A1	A2	A3
CAPEX	- €	- €	- €
OPEX	- €	664,000 €	398,400 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	- €	664,000 €	398,400 €

2.2.3. Data storage models

2.2.3.1. Baseline and scope

This section aims to describe the cost analysis for the policy approach "Data storage models". It considers the impact for the following economic stakeholders:

- Manufactures and importers
- Competent authorities

The data storage is a new solution with capabilities that do not currently exist in the European supply chain of tobacco products (i.e. storage of trade and traceability events reported by the economic operators and providing surveillance features to the competent authorities based on that data). The data storage costs are mainly based on the sizing estimation, which is based on a standard data model that provides information about the average size of the different messages. Hence, the costs are independent of which tobacco product is actually reported because they simply imply different identifiers. The objective of the storage sizing estimation is to determine the most demanding requirements, which will later be used to calculate the infrastructure costs needed to accommodate the annual amount of data.

This analysis does not include the costs to report the required events. These costs are estimated in the "Allowed delays in reporting events" section.

2.2.3.2. Assumptions

The assumptions for the data storage model are divided in the following groups:

- Assumptions regarding the estimation of the data storage sizing
- Assumptions regarding the estimation of the data storage infrastructure
- Assumptions regarding the estimation of the labour costs for the competent authorities

2.2.3.2.1. Assumptions regarding the estimation of the data storage sizing

Before detailing the sizing assumptions, the following remark shall be considered:

- *The formats of the messages exchanged will be specified in Work Package 3. However, to realise the sizing calculations, the average size of each message type is based on the standard ISO/IEC 19987:2015 EPC Information services* (ISO/IEC 19987:2015 EPCIS, 2016).

The assumptions needed to estimate the global sizing requirements of the annual data storage are included in the table below:

Assumption	Value	Source
Number of messages received at unit packet level according to the following business process: "Report generation of the UID at unit packet level.	1	Business Processes section of this Study
Average message size, in bytes, when reporting a traceability event at unit packet level. It is based on the data model specification of the ISO/IEC 19987:2015 EPC Information services standard.	1,024	ISO/IEC 19987:2015 EPC Information services standard (ISO/IEC 19987:2015 EPCIS, 2016)
Average message size, in bytes, when reporting an event with aggregation information. It is based on the data model specification of the ISO/IEC 19987:2015 EPC Information services standard.	3,072	ISO/IEC 19987:2015 EPC Information services standard (ISO/IEC 19987:2015 EPCIS, 2016)
Average message size, in bytes, when reporting an event about reverse logistics or re-packaging. It is based on the data model specification of the ISO/IEC 19987:2015 EPC Information services standard.	3,584	ISO/IEC 19987:2015 EPC Information services standard (ISO/IEC 19987:2015 EPCIS, 2016)
Average message size, in bytes, for exchanging trade	10,240	ISO/IEC 19987:2015 EPC

information. It is based on the data model specification of the ISO/IEC 19987:2015 EPC Information services.		Information services standard (ISO/IEC 19987:2015 EPCIS, 2016)
Percentage of reverse logistics events over the total events. *Since this is a mature market, with no expirations of product, no heavy seasonality and no quality or customisation issues, 1% could reflect in a conservative way a practice of reverse logistics that is quite odd in this industry.*	4%	(Greve & Davis, 2013)
Size in bytes of the UID unit packet as required by the TPD according to the academic sizing approach of Interim Report I.	161	Interim Report I (everis, 2016)
Size in bytes of the UID of other aggregation levels according the Serial Shipping Container Code (SSCC).	20	GS1 Serial Shipping Container Code (SSCC) (GS1 SSCC, 2015)
Average number of change of custody events that the tobacco products go through from the point of manufacture, up to the retailer. *On one hand, the answers received from the manufacturers consultation indicate an average of four change of custody events along the supply chain of tobacco products. On the other hand, according to the TPD, each change of custody would imply two events: dispatch and receipt.*	8	(European Commission - Feasibility Study, 2015) (Directive 2014/40/EU of the European Parliament and of the Council, 2014)
Percentage of the original size after compression *It should be noted that the final compression rate depends on the nature of the data stored, but many benchmarks are coincident with a high compression when dealing with XML data*.	65%	Compression benchmarks: (MongoDB, 2015) (MongoDB, 2015) (IBM, 2011) (Augeri & Bulutoglu, 2007)
Percentage of trade events at a carton level (only considered in the pessimistic storage sizing scenario)	50%	Contractor's expertise.
Percentage of trade events at a mastercase level (only considered in the pessimistic storage sizing scenario)	50%	Contractor's expertise.

There is a major factor to consider for the sizing estimation: the **aggregation level**. It is not yet known yet which level of aggregation will be most frequently adopted for reporting when the Tracking and Tracing System is deployed. Thus, the storage sizing is modelled according to the following aggregation level scenarios:

- **Optimistic**. This scenario implies that the data storage solution receives reports at a ***pallet*** level. As such, less data is transmitted and stored than reporting at other aggregation levels.
- **Realistic**. This scenario implies that the data storage solution receives reports at ***mastercase*** level.
- **Pessimistic**. This scenario implies that the data storage solution receives reports only at a ***carton*** level[16]. The sizing calculation assumes that the reporting related to trade information, which is received when the change of chain of custody happens, will happen 50% at a carton level and 50% at a mastercase level. As

[16] Although aggregation at carton level is not expected for cigarettes, this is a valid scenario for other types of tobacco products, which are manufactured and distributed in smaller quantities.

such, although this scenario is pessimistic, is also embracing some realistic operational assumptions. This scenario would require more resources for transmitting, processing and storing. It should be noted that some of the economic operators of the supply chain of tobacco do not currently operate at this level of aggregation.

2.2.3.2.2. Assumptions regarding the estimation of the data storage infrastructure

The cost analysis of each model considers not only the physical storage needs related to the estimated sizing, but also the processing infrastructure necessary to manage such data. As such, the costs are modelled on the basis of common data centre best practices where separate tiered physical data storage areas are created, thus delivering the required combinations of performance, capacity and resilience:

- Establishment of a "hot" layer with data that is more frequently accessed (i.e. shorter response times).
- Establishment of a "cold" layer with data that is less frequently accessed (i.e. longer response times).

The following table includes all the assumptions needed to estimate the infrastructure, including hardware and software costs, required by the data storage.

Concept	Value	Source
Reference server characteristics for storage and processing	Dual Intel® Xeon® E5-2620V1, 256GB RAM, 2 × 1TB HDD, 1Gbps	Sample dedicated server (iweb, 2017)
TB managed per server in the "hot" storage tier	2 TB	See above the characteristics of the reference server
Retention period (years)	10	Information reported by Austria in the First Workshop with MS
Additional servers per data storage solution. *It is assumed one server per each of the following capabilities: cluster manager, high availability, "cold" storage tier access manager, Cross Cutting Services, Recording Interfaces, Data Management and Consumer Interfaces.*	7	It is based on the main components identified in the System Architecture section
Number of servers in the Federation Services solution. *It is assumed there will be one server per each of the following capabilities: cluster manager, high availability, Cross Cutting Services, Discovery Service, Service Registry and Repository Router.*	6	It is based on the main components identified in the definition of the B2 and B3 data storage models
Years of data in the "hot" storage tier. *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise on designing large-scale enterprise databases. Work Package 3 should specify the technical requirements to establish this figure more accurately.*	1	There is no available a specific source for this figure. It has been allocated according to the Contractor's expertise on designing large-scale enterprise databases

Number of data storage solutions at options B2 and B4. *At this stage, it is very difficult to anticipate the most likely number of manufacturers/importers willing to have their own data storage solution. For the sake of objectivity, and for conducting the current costs estimation, this study assumes that the number of data storage solutions will be proportional to the market share at EU level. As such, since four manufacturers have 90% of EU market share, it could be assumed that each of them will have its own repository and that other three repositories would be established by the rest of the manufacturers/importers, assuming some sort of synergies between groups of manufacturers/importers in order to share the repository costs.*	7	Tobacco EU market share (European Commission - Economic analysis of tobacco products, 2013)
Number of data storage solutions at option B3. *At this stage, it is very difficult to anticipate the most likely number of Member States willing to have their own data storage solution. For the sake of objectivity, and for conducting the current costs estimation, this study assumes that the number of data storage solutions will be proportional to the consumption share per Member State at EU level. As such, since 14 Member States have an individual share of more than 2% of the EU consumption market and represent a total of 90% of EU consumption of tobacco products, it could be assumed that each of them will have its own repository. Five additional repositories will be established for the rest of Member States, assuming that one repository will be shared by three Member States.*	19	Estimation of the market size per Member State based on the Inception Impact Assessment
Operational support per data storage solution. (OPEX) *Since at this stage the definition of the Tracking and Tracing System remains at a very high level, the value has been allocated according to the Contractor's expertise in operating large-scale systems.*	5 FTE per year	Team Operational experience
Implementation of the data repository. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise in large-scale enterprise databases.*	6 FTE per one year	Team Operational experience
Customisation of the EPCIS server software. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise in software development.*	4 FTE per one year	Team Operational experience
Implementation of basic surveillance services. It includes the following features: dashboard, query tool, notifications and reporting. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise in software development. Work Package 3 will specify the technical requirements to establish this figure more accurately.*	6 FTE per one year	Team Operational experience.
Implementation of the data management activities. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has*	6 FTE per one year	Team Operational experience

been allocated according to the Contractor's expertise in software development and database implementation. Work Package 3 will specify the technical requirements to establish this figure more accurately.		
Implementation of the discovery service. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise in software development. Work Package 3 will specify the technical requirements to establish this figure more accurately.*	6 FTE per one year	Team Operational experience.
Implementation of the synchronisation process. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, the value has been allocated according to the Contractor's expertise in software development and database implementation. Work Package 3 will specify the technical requirements to establish this figure more accurately.*	6 FTE per one year	Team Operational experience
Implementation of the cross-cutting services. (CAPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise in software development. Work Package 3 will specify the technical requirements to establish this figure more accurately.*	4 FTE per one year	Team Operational experience
Software maintenance support (i.e. corrective and evolutionary). (OPEX) *Since at this stage the definition of the Tracking and Tracing System is at a very high level, this figure has been allocated according to the Contractor's expertise on software development and applications maintenance. Normally, it is an average, 10% at minimum, of the total development effort.*	3 FTE per year	Team Operational experience

2.2.3.2.3. Assumptions regarding the estimation of the competent authorities' costs

The costs for the competent authorities are based on the labour costs of the different tasks that have to be performed by the competent authorities.

The following table includes all the assumptions needed to estimate the costs of the competent authorities' tasks related to the data storage.

Concept	Value	Source
FTE effort to conduct surveillance activities per data storage solution. (OPEX)	3 FTE per year	Team Operational experience
FTE effort to approve, monitor and evaluate the third party data storage provider B1 and B4 (refers only to the central repository). (OPEX)	1 FTE per year	Team Operational experience
FTE effort to approve, monitor and evaluate the third party data storage provider in B2, B3 and B4 (refers to the distributed data storages). (OPEX)	0.5 FTE per year	Team Operational experience
FTE effort for governance activities per data storage solution. (OPEX)	2 FTE per year	Team Operational experience

2.2.3.3. Figures, volumes and unitary costs

The following tables present the unitary cost per item and by type of cost (CAPEX, OPEX).

Competent Authorities - OPEX

Concept	Type	Value	Source
EU-28 Labour cost for employee of public administration	FTE/year	36,912.00 €	(Eurostat, 2013)

Manufacturers & Importers - OPEX

Concept	Type	Value	Source
Price per server in the "hot" storage tier (yearly leased quotation)	Leased server price for the "hot" tier/year	8,949 €	Dedicated server pricing hosted in the Union (iweb, 2017)
Subscription of the operating system per server (yearly)	Operating system price/year	750 €	Red Hat Enterprise Linux 7 for Servers Media (Red Hat, 2016)
Leased communication line between two facilities at 100Mbps (yearly)	Leased communication line/year	40,311 €	NTT Data Europe Reference price for a leased communication line between two European facilities (NTT Data, 2016)
FTE annual labour cost for operational activities in EU28	FTE operational support/year	55,181 €	(Eurostat, 2013) (Average Eurostat EU28 FTE price per year for Information Service activities)
FTE annual labour cost of a software developer in EU28	FTE software development/year	64,021 €	(Eurostat, 2013)
Cost for purchasing a third party audit for one system (yearly)	All data storage facilities	4,000 €	EC Impact Assessment on Directive 2001/83/EC (European Commission - Impact Assessment FMD, 2008)

Manufacturers & Importers - CAPEX

Concept	Type	Value	Source
Server for the "cold" storage tier (scales up to 3PB)	Price of the "cold" storage tier server	200,000 €	EMC VNX5800 storage tower (EMC, 2017)
"ISO/IEC 19987:2015 EPC Information services" open source implementation cost	Price of the EPCIS software component	0 €	Open Source Fosstrak EPCIS (FOSSTRAK, 2010)

2.2.3.4. Results

2.2.3.4.1. Data storage sizing estimation

Firstly, it should be noted that the following sizing estimation is based on the messages that are expected to be exchanged with the economic operators as required by the TPD. Additional use case scenarios of data usage by the competent authorities are not considered yet. This sizing will be reviewed in Work Package 3, in light of the usage needs that may arise. It is expected that the impact of the competent authorities' use scenarios with regards to sizing would be included in the indexes, since additional indexes for reading purposes will be created to facilitate the efficiency of queries.

Below, the yearly sizing requirements have been estimated for each aggregation level scenario. The objective is to determine which scenario is the most demanding in terms of sizing. Later, the highest sizing estimation will be used to calculate the infrastructure costs needed to accommodate the annual amount of data.

The different aggregation levels directly impact the number of events received in relation to the aggregation, reverse logistics, dispatch and receipt reporting. As such, the following rules apply:

- Optimistic scenario: reporting at a pallet level of dispatch and receipt events.
- Realistic scenario: reporting at a mastercase level of dispatch and receipt events.
- Pessimistic scenario: reporting at a carton level of dispatch and receipt events.

Although there currently are some manufacturers that can report at a mastercase level at minimum, this study considers it to be more prudent to size and design the data storage according to the worst scenario requirements (i.e. reporting at a carton level at maximum). This ensures that the data storage adequately supports the events reported by all economic operators, irrespective of their aggregation level.

Currently, the operators of the distribution chain deal with disaggregation and re-aggregation at different aggregation packaging levels in order to optimise their reporting activities. We considered the following average of re-aggregation activities:

- 25% of mastercase distribution
- 50% of pallet distribution

These re-aggregation averages will be applied to the sizing calculation.

Calculations for the number of events to report aggregation information

Aggregation level	Number of aggregation events per level (yearly)
Carton	2,964,140,000
Mastercase	59,282,800
Pallet	1,185,656

Calculations of the data storage sizing

Type of data to store	Optimistic - Total size (TB) yearly	Realistic - Total size (TB) yearly	Pessimistic - Total size (TB) yearly
Events at unit packet level	17.94	17.94	17.94
Aggregation events	5.49	5.49	5.38
Reverse logistics and re-packaging events	0.29	0.29	0.28
Indexes	0.05	2.64	67.27
Events with trade information	4.34	4.34	4.34
Unique identifiers at unit packet level	0.06	0.05	0.05
Unique identifiers of aggregation levels	4.40	4.40	4.39
TOTAL	**32.57**	**35.15**	**99.67**

It should be noted that the high cardinality to be managed by Tracking and Tracing System (i.e. 29,641,400,000 unit packets of tobacco products) has a big impact on the sizing due to the following:

- One report is received at a unit packet level (i.e. business process of reporting the generation of a unique identifier at unit packet level) as a minimum. Hence, the data storage has to deal with 17.94 TB of data yearly with regards to this specific event.
- As a minimum, 4.34 TB are required yearly to store the unique identifiers at unit packet level.

It is important to remark that the format of the message to be exchanged will not be defined until Work Package 3. For the calculation, the widely adopted standard ISO/IEC 19987:2015 EPC Information services, which is based on XML (W3C XML, 2016), has been used as a reference. The message format must be defined during Work Package 3 and shall be optimised as much as possible in order to reduce the impact of the messages on the storage solutions.

The sizing estimation of the pessimistic scenario (i.e. 99.67 TB of new data yearly) will be used as basic input to conduct the calculation of servers needed by each data storage model presented below.

Calculation of the servers needed by each data storage solution

For the calculation of servers, the following rules apply:

- Each data storage solution requires the following infrastructure:
  - Servers to manage exclusively the "hot" storage tier. The number of servers needed for this can be calculated as follows: (number years of "hot" data) * (amount of TB of new data stored yearly in that solution) / (TB managed per server in the "hot" storage tier).
  - Supplementary servers to support the additional specific functionalities expected from the data storage solution. This figure is introduced earlier in the assumptions section.
  - Server to host the "cold" storage tier. This server will be considered later in the total cost calculation as CAPEX.
- The amount of new data to be stored yearly in the "hot" tier by each data storage solution is calculated as follows: (total data size estimated previously) / (number of data storage solutions that comprise the model). In this respect, it should be remarked that the real distribution of data only will be known when the data storage solutions are finally established;
- The number of data storage solutions per model is introduced earlier in the assumptions section (i.e. B1 has 1, B2 has 7, B3 has 19 and B4 has 7);
- Supplementary servers are required to run the functionalities expected by the Federation Services solution of the B2 and B3 models. This figure is presented earlier in the assumptions section and is based on the preliminary capabilities identified;
- The number of servers for the Surveillance solution of B4 is the same as B1.

Concept	Servers B1	Servers B2	Servers B3	Servers B4
Servers to manage the "hot" tier per each data storage solution	50	8	3	8
Supplementary servers per each data storage solution	7	7	7	7
Total servers of the data storage solution(s)	57	105	190	105
Supplementary servers per model		6	6	57
TOTAL servers per model	**57**	**111**	**196**	**162**

2.2.3.4.2. Data storage infrastructure and auditing

The CAPEX calculations presented below include the following concepts:

- Software development efforts for the main components required by the different options of the data storage models;
- Hardware infrastructure for the "cold" storage.

It should be noted that all the calculations depend directly on the number of distributed data storage solutions to form part of the final Tracking and Tracing System.

Manufacturers & Importers - CAPEX

	B1	B2	B3	B4
EPCIS server software	0 €	0 €	0 €	0 €
Customisation of the EPCIS server software	256,084 €	1,792,588 €	4,865,596 €	2,048,672 €
Implementation of basic surveillance services	384,126 €	2,688,882 €	7,298,394 €	3,073,008 €
Implementation of the data management activities	384,126 €	2,688,882 €	7,298,394 €	3,073,008 €
Implementation of the discovery service	0 €	2,688,882 €	7,298,394 €	0 €
Implementation of the synchronisation process	0 €	0 €	0 €	3,073,008 €
Implementation of the cross-cutting services	256,084 €	1,792,588 €	4,865,596 €	2,048,672 €
Implementation of the recording interfaces	128,042 €	896,294 €	2,432,798 €	1,024,336 €
Implementation of the data repository	384,126 €	2,688,882 €	7,298,394 €	3,073,008 €
Server for the "cold" storage tier	200,000 €	1,400,000 €	3,800,000 €	1,600,000 €
TOTAL	**1,992,588 €**	**16,636,998 €**	**45,157,566 €**	**19,013,712 €**

The OPEX calculations presented below include the following concepts:

- Fees for the operating systems;
- Operational support on premise;
- Software maintenance efforts;
- Dedicated communication line. The communication model quoted assumes that for B2, B3 and B4 models, each data storage solution needs a high speed communication line only with the central solution (namely Federation Services or Surveillance), as a star network topology, because this central solution would receive a large amount of data from the distributed data storage solutions;
- Leased servers for each data storage model;
- Auditing of the third party data storage provider activities.

As before, it should be noted that all the calculations depend directly on the number of distributed data storage solutions to form part of the final Tracking and Tracing System.

Manufacturers & Importers - OPEX

	B1	B2	B3	B4
Operating system	42,750 €	83,250 €	147,000 €	121,500 €
Operational support on premise	275,905 €	2,207,240 €	5,518,100 €	2,207,240 €
Software maintenance support (i.e. corrective and evolutionary)	192,063 €	1,344,441 €	3,649,197 €	1,536,504 €
Communication line at 100Mbps	0 €	282,177 €	765,909 €	282,177 €
Servers per model	510,102 €	993,357 €	1,754,036 €	1,449,765 €
Auditing	4,000 €	32,000 €	80,000 €	32,000 €
TOTAL	**1,024,820 €**	**4,942,465 €**	**11,914,242 €**	**5,629,186 €**

2.2.3.4.3. Competent authorities

The costs of the competent authorities presented below include the following concepts:

- Estimation of activities related to approving, monitoring and evaluating the third party data storage provider;
- Estimation of activities related to conducting surveillance tasks;
- Estimation of activities related to the governance of the data storage.

Competent Authorities - OPEX

	B1	B2	B3	B4
Surveillance activities effort estimation	110,736 €	885,888 €	2,214,720 €	885,888 €
Effort to approve, monitor and evaluate the third party data storage provider	36,912 €	147,648 €	369,120 €	184,560 €
Governance of the data storage	73,824 €	590,592 €	1,476,480 €	590,592 €
TOTAL	**221,472 €**	**1,624,128 €**	**4,060,320 €**	**1,661,040 €**

2.2.3.5. Summary

Manufacturers & Importers

	B1	B2	B3	B4
CAPEX	1,992,588 €	16,636,998 €	45,157,566 €	19,013,712 €
Annualised cost	332,098 €	2,772,833 €	7,526,261 €	3,168,952 €
OPEX	1,024,820 €	4,942,465 €	11,914,242 €	5,629,186 €
TOTAL ANNUALISED	1,356,918 €	7,715,298 €	19,440,503 €	8,798,138 €
TOTAL ANNUALISED PER UNIT PACKET	0.000046	0.000260	0.000656	0.000297

Competent Authorities

	B1	B2	B3	B4
OPEX	221,472 €	1,624,128 €	4,060,320 €	1,661,040 €

Total

TOTAL	B1	B2	B3	B4
CAPEX	1,992,588 €	16,636,998 €	45,157,566 €	19,013,712 €
OPEX	1,246,292 €	6,566,593 €	15,974,562 €	7,290,226 €
Annual depreciation	332,098 €	2,772,833 €	7,526,261 €	3,168,952 €
Annualised total costs (OPEX + depreciation)	1,578,390 €	9,339,426 €	23,500,823 €	10,459,178 €
Total annualised cost per unit marked	0.000053 €	0.000315 €	0.000793 €	0.000353 €

2.2.4. Allowed data carriers

2.2.4.1. Baseline and scope

This section aims to describe the cost analysis for policy approach "C - Allowed Data Carriers". It considers the impact for the following economic stakeholders:

- Manufactures and importers;
- Distribution chain operators:
  - Big distributors and wholesalers;
  - Vending machine service organisations;
  - Mobile sales force organisations.

The cost analysis for policy approach "A - Governance Model" already takes into account the cost of the equipment required to print and verify the unique identifiers (at unit packet and aggregation packaging levels). Therefore, this cost analysis only takes into account the extra cost in printing and verifying equipment (for manufacturers, importers, big distributors and wholesalers) associated to the implementation of each policy option.

This cost analysis contemplates the economic impact of the equipment required to correctly perform the T&T activities in the distribution chain operators:

- Printing & verifying activities:
  - Additional cost in printing equipment;
  - Additional operational cost (ink, repairs and maintenance) for printing and verifying activities.
- Scanning activities:
  - uTrack kit (equipment used to read the tracking and tracing information and transmit it to the ERP system).

- Additional human resources operational cost for scanning activities in the distribution chain.

- Administration activities:
  - Registration costs.

For the purpose of this analysis the same type activities in the distribution chain for all the tobacco products have been contemplated (including cigars, RYO, pipe tobacco and smokeless tobacco).

2.2.4.2. Assumptions

The assumptions for the cost analysis of allowed data carriers are divided into two groups: printing and verifying activities, and scanning activities. It is assumed that these assumptions are valid for the production and distribution of all types of tobacco products.

2.2.4.2.1. Assumptions regarding printing and verifying activities

These assumptions consider the printing activities carried out in the manufacturer, importer and big distributor facilities (due to re-aggregation processes).

The nature of the different options has a direct influence on the costs of the equipment. In terms of capital expenditures, the following effect has been detected:

- A higher number of data carriers reduces the cost of printing and verifying equipment because:
  - The equipment currently dedicated to similar activities in manufacturing facilities can be re-used. A higher variety of allowed data carriers increases the possibilities of re-use due to the wider range of equipment permitted for these processes.
  - A wider variety of allowed data carriers permits more efficient selection of the required equipment.

In order to model the described effects in the cost analysis, the following variations in costs have been estimated. The estimation has been based on the points previously highlighted. As the types of allowed data carriers are not decided, the estimation can only reflect the influence of the number of allowed data carriers in each option.

	Actual situation	C1	C2	C3	C4	C5
Reduction of equipment cost due to reutilisation	-	-	-	-20%	-20%	-40%

2.2.4.2.2. Assumptions regarding scanning activities

This assumption concerns the scanning activities for the distribution chain operators.

The cost of the equipment used in scanning activities is highly influenced by the type of data carriers to be read. The variation in cost depends on the following effects:

- Scanners are based in different technologies that enables reading a certain set of data carriers. A wider range of allowed data carriers increases the probability of

needing different types of scanners to read them all, resulting in a higher cost of equipment.

- Option C1 cannot include 1D data carriers for the aggregation packaging levels. As the most widely used data carriers in transportation and logistics are 1D barcodes, there is a need for additional scanners for the distribution chain operators.
- The effect of the optional addition of data carriers in order to improve the efficiency of the distribution chain is not included in the cost analysis because it depends on the willingness of the manufacturers to include them.

As stated in the assumptions regarding printing and verifying activities, the estimation has been based on the number of the allowed data carriers per option, trying to reflect the points highlighted before.

	Actual situation	C1	C2	C3	C4	C5
Increase of uTrack cost due to the number of data carriers	-	**25%**	-	**20%**	**20%**	**60%**

The analysis identifies the different equipment needs for the distribution chain operators:

- Big distributors: 3 uTrack kits per facility;
- Small and medium distributors: 1 uTrack kit per facility;
- Vending machine service organisations: 1 uTrack kit per vehicle, only 50% of the total vans will need to buy uTrack kits, assuming that each operator holds a number of service vans.
- Mobile sales force organisations: 1 uTrack kit per vehicle, only 50% of the total vans will need to buy uTrack kits, assuming that each operator holds a number of service vans.

The additional human resources operational costs must also be taken into account. In order to do so, the impact of these activities in the operations of the distribution chain has been estimated. Four change of custody events along the supply chain of tobacco products have been identified (European Commission - Feasibility Study, 2015). From here, the involved agents are: manufacturer, level 1 distributor, level 2 distributor, and retailer.

The cost analysis of the governance model already considers the operational activities for the manufacturer, and the retailer activities are out of the scope of this study. Therefore, this calculation only estimates the impact of the level 1 and 2 distributors.

The team has estimated that the level 1 distributors are "Big distributors and Wholesalers", and the level 2 distributors are divided in "Big distributors and Wholesalers", "Vending Machines Service Vans" (if the vending machines are permitted in the country), and "Mobile Salesforce Units".

Custody of the tobacco products along the supply chain		
Countries	**Level 1 Distributor**	**Level 2 Distributor**
Countries where vending machines are permitted (Nomisma, 2012). (Germany, Spain, Portugal, Netherlands,	100% Big distributors and wholesalers	50% Big distributors and wholesalers 25% Vending Machines Service

Italy, Belgium, Austria, Czech Republic, Malta, Luxembourg)		Vans 25% Mobile Salesforce Units
Rest of the countries		100% Big distributors and wholesalers

These activities correspond to the reporting of receiving or dispatching tobacco products (in their corresponding level of aggregation). They represent the effect of the legal consumption of each country (it is assumed that the exportations outside the EU do not follow this distribution flow) in the distribution chain. In the following table, the aggregation levels utilised in those activities have been estimated.

Level of aggregation for the inbound and outbound activities in the distribution chain		
	INBOUND	**OUTBOUND**
Level 1 Distributor	100% Pallet	75% Pallet 25% Mastercase
Level 2 Distributor	75% Pallet 25% Mastercase	75% Mastercase 25% Carton

The operational time required to correctly perform the scanning activities has also been estimated, based on the volume and physical characteristics of the aggregation levels. The estimation shows a capacity of scanning of 45 cartons per minute; 15 mastercases per minute and 5 pallets per minute.

Finally, registration costs will be incurred by the operators that are not currently registered, estimated to be 50% of the distribution entities

2.2.4.3. Figures, volumes and unitary costs

Most of the unitary costs used in this analysis were specified in the introductory section "Common parameters and general assumptions".

However, some unitary costs are specific to the calculations carried out in this analysis (registration costs in distribution chain operators), and are presented in the table below.

Wholesalers & Big Distributors - OPEX

Concept	Type	Minimum	Maximum	Selected Value	Source
Registration costs	All distributors and wholesalers	-	-	3,000€	Feasibility Study (European Commission - Feasibility Study, 2015)

The hourly labour costs in the wholesale and retail trade (Eurostat, 2013) and the consumption per country (Transcrime, Joint Reaseach Centre on Transational Crime, 2015) are reviewed in order to calculate the additional human resources operational costs. Also, it is assumed that the distribution activities for level 1 and 2 distributors will take place in the consumption country.

	Hourly labour costs	Legal Domestic Sales (millions of people)
Austria	27.49 €	683.45
Belgium	37.64 €	525.40
Bulgaria	3.11 €	545.75
Croatia	8.15 €	276.60
Cyprus	14.10 €	69.85
Czech Republic	9.29 €	945.11
Denmark	37.66 €	282.11
Estonia	7.88 €	93.85
Finland	29.18 €	211.49
France	29.71 €	2,269.29
Germany	27.16 €	4,001.43
Greece	14.63 €	839.51
Hungary	7.01 €	387.27
Ireland	22.15 €	152.23
Italy	24.07 €	3,588.70
Latvia	5.30 €	96.28
Lithuania	5.17 €	155.49
Luxembourg	25.94 €	63.93
Malta	9.57 €	27.22
Netherlands	27.90 €	536.97
Poland	6.15 €	2,059.07
Portugal	12.11 €	399.66
Romania	3.77 €	1,044.81
Slovakia	8.14 €	346.27
Slovenia	14.81 €	186.70
Spain	17.97 €	2,492.67
Sweden	36.51 €	300.27
United Kingdom	17.65 €	1,814.46

2.2.4.4. Results

This subchapter shows the calculations for the CAPEX and OPEX for all the economic operators included in the cost analysis of allowed data carriers.

Manufacturers and Importers - CAPEX

	C1	C2	C3	C4	C5
Unit packet printer & installation – High speed production lines	- €	- €	- 2,967,000 €	- 2,967,000 €	- 5,934,000 €
Unit packet printer & installation – Low -medium speed production lines	- €	- €	- 6,063,900 €	- 6,063,900 €	- 12,127,800 €
Cost of printing carton - High speed production lines	- €	- €	- 1,031,927 €	- 1,031,927 €	- 2,063,854 €
Cost of printing carton – Low - medium speed production lines	- €	- €	- 1,324,300 €	- 1,324,300 €	- 2,648,600 €
Cost of printing mastercase - High speed production lines	- €	- €	- 104,328 €	- 104,328 €	- 208,656 €
Cost of printing mastercase – Low - medium speed production lines	- €	- €	- 662,150 €	- 662,150 €	- 1,324,300 €
Pallet label printing – All production lines	- €	- €	- 199,200 €	- 199,200 €	- 398,400 €
TOTAL	- €	- €	-12,352,805 €	-12,352,805 €	-24,705,610 €

Wholesalers and Big Distributors - CAPEX

	C1	C2	C3	C4	C5
Case and pallet label printing – Big distributors	- €	- €	- 1,384,200 €	- 1,384,200 €	- 2,768,400 €
uTrack kit – Big facilities	86,512,500 €	69,210,000 €	83,052,000 €	83,052,000 €	110,736,000 €
uTrack kit – Small - medium facilities	67,287,500 €	53,830,000 €	64,596,000 €	64,596,000 €	86,128,000 €
TOTAL	153,800,000 €	123,040,000 €	146,263,800 €	146,263,800 €	194,095,600 €

Wholesalers and Big Distributors - OPEX

	Option 1	Option 2	Option 3	Option 4	Option 5
Additional HR operational costs	4,194,362 €	4,194,362 €	4,194,362 €	4,194,362 €	4,194,362 €
Registration cost – All entities	3,675,000 €	3,675,000 €	3,675,000 €	3,675,000 €	3,675,000 €

Vending machine service organisations - CAPEX

	C1	C2	C3	C4	C5
uTrack kit – All organisations	12,150,000 €	9,720,000 €	11,664,000 €	11,664,000 €	15,552,000 €

Vending machine service organisations - OPEX

	Option 1	Option 2	Option 3	Option 4	Option 5
Additional HR operational costs	894,470 €	894,470 €	894,470 €	894,470 €	894,470 €

Mobile sales force organisations - CAPEX

	C1	C2	C3	C4	C5
uTrack kit – All organisations	22,931,250 €	18,345,000 €	22,014,000 €	22,014,000 €	29,352,000 €

Mobile sales force organisations - OPEX

	Option 1	Option 2	Option 3	Option 4	Option 5
Additional HR operational costs	894,470 €	894,470 €	894,470 €	894,470 €	894,470 €

It has to be assumed that vending machine service organisations and mobile sales force organisations do not incur any additional operational expenditure caused by the implementation of the Tracking and Tracing System because they do not carry out any re-aggregation activities.

2.2.4.5. Summary

The summary of allowed data carriers shows the cost analysis for the two types of economic operators.

Manufacturers & Importers

Concerning the manufacturers and importers the most favourable option is C5, followed by C3 and C4.

	C1	C2	C3	C4	C5
CAPEX	**- €**	**- €**	**- 12,352,805 €**	**- 12,352,805 €**	**- 24,705,610 €**
OPEX	**- €**	**- €**	**- €**	**- €**	**- €**
Annual depreciation	**- €**	**- €**	**- 2,058,801 €**	**- 2,058,801 €**	**- 4,117,602 €**
Total annualised	**- €**	**- €**	**- 2,058,801 €**	**- 2,058,801 €**	**- 4,117,602 €**
Total annualised per unit packet	**- €**	**- €**	**- 0.00007 €**	**- 0.00007 €**	**- 0.00014 €**

Distribution Chain Operators:

(Wholesalers and big distributors, vending machine services, mobile sales forces)

In regards to the distribution chain operators, the most favourable options are C1 and C2, followed by C3 and C4.

	C1	C2	C3	C4	C5
CAPEX	188,881,250 €	151,105,000 €	179,941,800 €	179,941,800 €	238,999,600 €
OPEX	9,658,304 €	9,658,304 €	9,658,304 €	9,658,304 €	9,658,304 €
Annual depreciation	31,480,208 €	25,184,167 €	29,990,300 €	29,990,300 €	39,833,267 €
Total annualised	41,138,512 €	34,842,471 €	39,648,604 €	39,648,604 €	49,491,571 €
Total annualised per unit packet	0.00139 €	0.00118 €	0.00134 €	0.00134 €	0.00167 €

Total

The following table shows the total cost for this policy approach. It can be stated that the most favourable options are C1 and C2, followed by C3 and C4.

	C1	C2	C3	C4	C5
CAPEX	188,881,250 €	151,105,000 €	167,588,995 €	167,588,995 €	214,293,990 €
OPEX	9,658,304 €	9,658,304 €	9,658,304 €	9,658,304 €	9,658,304 €
Annual depreciation	31,480,208 €	25,184,167 €	27,931,499 €	27,931,499 €	35,715,665 €
TOTAL ANNUALISED	41,138,512 €	34,842,471 €	37,589,803 €	37,589,803 €	45,373,969 €
TOTAL ANNUALISED PER UNIT PACKET	0.00139 €	0.00118 €	0.00127 €	0.00127 €	0.00153 €

2.2.5. Allowed delays in reporting events

2.2.5.1. Baseline and scope

This section describes the cost analysis for the policy approach "Allowed delays in reporting events". It considers the impact for the following economic stakeholders:

- Manufactures and Importers
- Wholesalers and Distributors
- Competent Authorities

The cost analysis has been performed taking into account the economic stakeholders that actually incur costs, independently of whom is held ultimately responsible for the cost. For example, article 15.7 of the TPD states that the manufacturers shall provide all economic operators with the equipment that is needed for the recording of movements of

tobacco products. The cost of this equipment is calculated for each of the economic operators.

The event reporting process is a new system that implements capabilities that currently do not exist in the supply chain of tobacco products. The costs of the reporting events are mainly based on the hardware acquisition, software development to collect/receive the event data from the legacy system and transmit it to the data storage solution, and on the cost of support services in order to monitor and maintain the data reporting process. Hence, the costs are independent of which tobacco product is actually reported because this simply implies different identification data. The objective of the estimation is to determine the cost for each option, and whether they imply more or less demanding requirements, which will be used later to calculate the infrastructure costs needed to integrate and collect data from legacy systems, buffer and transmit data.

This analysis does not include the following cost:

- Estimation of costs necessary to store the required data in the global Tracking and Tracing System. These costs are estimated in the "Data storage model" section.

Cost calculation for the economic operators (manufacturers, importers, wholesaler and distributors)

As already pointed out, it is expected that every event must be reported to the data storage prior to any movement of goods to another facility or any change of custody. Therefore, in case of absence of information on these events, it is envisaged that the risk of product movement stoppage by the competent authorities will increase correspondently with the delay. This stoppage can last until all events have arrived at the data storage. Undoubtedly, this product stoppage will impact the involved economic operators. The exact cost cannot be calculated at this moment, which is still a qualitative cost. However, it is possible to be sure of the burden when considering the value of the freight and the number of hours or even days of the stoppage. Therefore, this possible intangible cost must be taken into account, despite the calculations shown later in this section.

2.2.5.2. Assumptions

The assumptions for the 'Allowed delays in reporting events' are divided into the following two groups:

- Assumptions regarding the estimation of the hardware;
- Assumptions regarding the estimation of the software.

These assumptions are separated according to the type of cost: capital expenditures (CAPEX) and operational expenditures (OPEX).

2.2.5.2.1. Assumptions regarding hardware

Capital expenditures

The nature of the different options (D1, D2 and D3) has a direct influence on the cost of the equipment. In terms of capital expenditures, the following effect has been detected:

- The higher number of servers in option D1 will deliver a solution with high availability.

In order to model the described effect in the cost analysis, the following variations in costs have been estimated.

	Actual situation	D1	D2	D3
Number of servers per facility	**-**	**2**	**1**	**1**

For the total hardware cost, it is assumed that every manufacturer or importer facility and every wholesaler and distributor warehouse will acquire a new server in accordance with the allowed delay option, and likewise, with the monitoring and support.

For other related item costs, the following assumptions are considered:

- **Internet Connection Link**: It is assumed that the economic operators' facilities already possess access to the Internet. As presented previously, high connection rates are not required; a standard market Internet connection, such as ADSL or 3G can support the expected throughput for all the given options.
- **Buffer Area Hard Disk**: Although the volume of data retention varies for each option, it is assumed that the minimum storage configuration of any server acquired will handle the data consumption for any allowed delay option. Therefore, the hard disk cost is already considered in the hardware acquisition for all options.

Operational expenditures

In terms of operational expenditures, the following effects have been detected:

- The complexity posed by option D1, demanding a system with high availability standards, requires more resources than options D2 and D3. Therefore, a higher number of servers with more intensive monitoring and support services, demanding 24x7 assistance, increases the cost. More intensive monitoring and support services can be described as mission critical support with priority access to Senior-Level Engineers, in order to get the necessary help more quickly. The streamlined process connects the system to Technical Support Engineers, with specialised experience in supporting this kind of environment. This technical support also aims to:
    - Prevent future issues from occurring with proactive account management: identifying trends, developing action plans and fast-track escalations;
    - Coordinate third-party relationships to minimise downtime with aggressive target response times of 30 minutes or less for Severity 1 issues and technical support whenever necessary, 24x7.
- In options D2 and D3, the same demanding level of support and monitoring is applied. As they allow a larger time lag to report the event data, starting from one day up to one week, the non-critical mission support can achieve the standards.

	Actual situation	D1	D2	D3
Increase of cost on hardware monitoring and maintenance support	**-**	**80%**	**-**	**-**

2.2.5.2.2. Assumptions regarding software

Capital expenditures

The nature of the different options (D1, D2 and D3) has a direct influence on the cost of software development. In terms of capital expenditures, the following effect has been detected:

- A more complex software development on option D1, in order to work on very high demanding environment, when compared with options D2 and D3.

In order to model the described effect in the cost analysis, the following variation in costs have been estimated, based on the principles of Halstead software development complexity measures (Qutaish & Abran, 2016) where the complexity measure is related to the complexity of the program to write or understand. Complexity is a multi-dimensional property of a program which cannot be captured by a single number. It would be wrong to use any one complexity measure as an indicator of program quality, or as a major driver in a cost or effort model (Zuse, 1991). The adoption of a complexity percentage delivers the required adjustment of option D1, due to the increase of function points effort estimation methodology (IFPUG, 2016), when compared with options D2 and D3. Thus, these last two options are considered to pose the same level of effort complexity, because developing software to deliver data on a daily basis requires the same effort as developing a software to deliver data on a weekly basis. The major difference is in regard to the volume of the data accumulated between each data transmission.

	Actual situation	D1	D2	D3
Software development complexity increment	**-**	**66%**	**-**	**-**

The final developed software can be reused by multiple economic operators. The non-reusable development part mainly applies to the legacy systems integration, where distinct sources and capabilities scenarios will demand custom adaptation for each individual implementation. Therefore, it is assumed that the software development effort cost is based on a percentage level of re-use. It is also assumed that the big manufacturers will develop their own solution, while the SMEs will use their association group to develop a reusable solution. Thus, a total of 19 independent groups of software development will be performed, taking into account the number of tobacco associations across Europe plus the number of big manufacturers, as shown in the following table:

Group	Quantity
Big Manufactures	4
Tobacco Manufacturers Associations	15 (CECCM, 2016)

Operational expenditures

In terms of operational expenditures, the following effects have been detected:

- The complexity posed by option D1 requires more resources to maintain than options D2 and D3, and therefore **increases the cost**. The higher number of required resources for option D1 can be described as the necessary environment for a solution working at mission critical level. As such, development, testing, deployment and distribution environments are more demanding and complex to maintain.

	Actual situation	D1	D2	D3
Increase of cost on software maintenance	**-**	**66%**	**-**	**-**

2.2.5.3. Figures, volumes and unitary costs

Hardware – CAPEX

The hardware cost is based on a standard market server with the following configuration:

Concept	Configuration	Minimum	Maximum	Selected Value	Source
Server Hardware	• Intel Xeon E5-2609 v4 1.7GHz 20M Cache 6.4GT/s QPI 8C/8T (85W) 1866MHz • 16GB RDIMM, 2400MT/s, Dual Rank, x8 Data Width • 1TB 7.2K RPM SATA 6Gbps 3.5in Hot-plug Hard Drive • RAID 0 for H330/H730/H730P with PERC H330 RAID Controller • Single, Hot-plug Power Supply (1+0), 495W • Linux Enterprise Server 12, Factory Install • Basic Deployment Manufacturer Service	1,500€	3,068€	2,284€	(Dell inc., 2016) (Ebuyer (UK) Limited, 2016)

Hardware – OPEX

Concept	Type	Minimum	Maximum	Selected Value	Source
Server Support and Monitoring per Year per Server	Mission Critical (D1)	1,442€	3,329€	2,386€	(Dell inc., 2016)
	Non-Mission Critical (D2 and D3)	806€	1,855€	1,331€	
Server Maintenance per Year per Server	Server Maintenance	228€			(Dell inc., 2016)

Software – CAPEX

The estimated number of effort hours is based on a high level overview of an integration and software development project. It is also important to consider that the level of complexity increases for option D1, impacting the effort estimations directly. An increase adjustment percentage of 66% is applied on top of the estimated effort to compensate the level of complexity imposed by that option. Options D2 and D3 pose the same level of development complexity.

Component	Type	Complexity	Qty	Effort (h)	Comments
Design of the system architecture	Others		1	240	Creation of the general solution architecture documentation
Validation of the system architecture	Others		1	80	Validation of the architecture documentation
Platform Installation	Others		1	80	Installation and test of basic software to start the implementation
PoC	Others		1	80	Proof of concepts to guarantee connectivity and basic solutions
Data Validation	Process	High	1	96	Implementation of the business process to perform data validation prior to sending to the Tracking and Tracing System
Duplicate Checks	Process	High	1	96	Implementation of the business process to perform duplicates check in order to avoid data duplication prior to sending to the Tracking and Tracing System
Contingency UI	View	Medium	2	96	Implementation of the contingency UI
Local Buffer Data Storage	Entity	Low	4	96	Implementation of the buffer data repository
Audit Trails	Entity	Low	4	48	Implementation of the audit data repository
Security	Process	High	1	64	Implementation of the security access module
Monitoring	Process	Medium	2	128	Implementation of the system monitoring module
Administration UI	View	Medium	4	192	Considering 4 views to access the configuration, security and monitoring functionalities
Configuration	Entity	Medium	4	192	Implementation of the system configuration
Integration	Process	High	4	384	Integration with other companies´ legacy software (e.g.: ERP/uTrack/WMS)
Data Inbound Endpoint	Service	Medium	1	72	Implementation of the data inbound endpoint
Data Outbound Endpoint	Service	Medium	1	72	Implementation of the data outbound endpoint

Total estimated hours effort	2048	**= 1.17 FTE**

The effort estimation above considers the following workload distribution:

Activity	Effort Workload Distribution
Analysis	20%
Design	30%
QA	25%
Documentation	10%
Deployment	5%
Management	10%

The following table presents the average annual labour cost of a software developer in EU28:

Concept	Configuration	Cost	Source
Software development	Annual labour cost of a software developer in EU28 (for 2012) – 1 FTE	64,021€	(Eurostat, 2013)

Software – OPEX

Concept	Type	Cost	Source
Software maintenance per year (10% of the development effort)	Mission Critical (66% over) (D1)	12,367€	(Eurostat, 2013)
	Non-Mission Critical (D2 and D3)	7,450€	

2.2.5.4. Results

This subchapter shows the calculations for the CAPEX and OPEX for each economic operator included in the cost analysis of the allowed delays in reporting events. First it will present the individual cost per each operator, and then it will present the global cost.

Hardware - CAPEX

The following table presents the costs to acquire the server hardware. Option D1 requires two servers in order to achieve the high availability standards, while options D2 and D3 require one server.

	D1	D2	D3
Quantity of servers	2	1	1
Unitary cost of the server hardware	2,284€		
CAPEX Hardware	**4,568€**	**2,284€**	**2,284€**

Hardware - OPEX

The following table presents the costs of monitoring, supporting and maintaining the server hardware. As explained before, option D1 requires mission critical monitoring and support, options D2 and D3 require non- mission critical monitoring and support, and the maintenance is considered to be 10% of the server price.

	D1	D2	D3
Number of servers	2	1	1
Support and monitoring (unitary cost per server)	2,385€	1,331€	1,331€
Server support and monitoring	**4,771€**	**1,331€**	**1,331€**
Server maintenance (10%)	457€	228€	228€
OPEX Hardware	**5,228€**	**1,559€**	**1,559€**

Software - CAPEX

	D1	D2	D3
Software development	123,665€	74,497€	74,497€
TOTAL	**123,665€**	**74,497€**	**74,497€**

Software - OPEX

	D1	D2	D3
Software maintenance (10%)	12,367€	7,450€	7,450€
TOTAL	**12,367€**	**7,450€**	**7,450€**

2.2.5.5. Summary

The summary of allowed delays in reporting events shows the cost analysis:

Manufacturers & Importers

	D1	D2	D3
Unitary hardware CAPEX per facility	4,568€	2,284€	2,284€
Number of facilities	332		
Total hardware CAPEX	**1,516,576€**	**758,288€**	**758,288€**
Unitary software CAPEX	123,665€	74,497€	74,497€
Number of individual groups of software development	19		
Total software CAPEX	**2,349,635€**	**1,415,443€**	**1,415,443€**

Total CAPEX	**3,866,211€**	**2,173,731€**	**2,173,731€**
Hardware monitoring and support	4,771€	1,331€	1,331€
Hardware Maintenance	457€	228€	228€
Unitary hardware OPEX (with no Annualised depreciation)	**5,228€**	**1,559€**	**1,559€**
Number of facilities	332		
Total hardware OPEX (with no annualised depreciation)	**1,735,630€**	**517,555€**	**517,555€**
Unitary software OPEX (with no annualised depreciation)	12,367€	7,450€	7,450€
Number of facilities	332		
Total software OPEX (with no annualised depreciation)	**234,964€**	**141,544€**	**141,544€**
Annual depreciation	644,368€	362,289€	362,289€
Total annualised (OPEX + depreciation)	**2,614,962€**	**1,021,388€**	**1,021,388€**
Total annualised per unit packet	**0.000088€**	**0.000034€**	**0.000034€**

Wholesaler & Distributors

	D1	D2	D3
Unitary hardware CAPEX per facility	4,568€	2,284€	2,284€
Number of facilities	7690		
Total hardware CAPEX	**35,127,920€**	**17,563,960€**	**17,563,960€**
Total CAPEX	**35,127,920€**	**17,563,960€**	**17,563,960€**
Hardware monitoring and support	4,771€	1,331€	1,331€
Hardware maintenance	457€	228€	228€
Unitary hardware OPEX (with no annualised depreciation)	**5,228€**	**1,559€**	**1,559€**
Number of facilities	7690		
Total hardware OPEX (with no annualised depreciation)	**40,201,782€**	**11,987,941€**	**11,987,941€**
Annual depreciation	5,854,653€	2,927,327€	2,927,327€
Total annualised (OPEX + depreciation)	**46,056,435€**	**14,915,268€**	**14,915,268€**
Total annualised per unit packet	**0.001554€**	**0.000503€**	**0.000503€**

Total

TOTAL	D1	D2	D3
CAPEX	38,994,131 €	19,737,691 €	19,737,691 €
OPEX	42,172,375 €	12,647,040 €	12,647,040 €
Annual depreciation	6,499,022 €	3,289,615 €	3,289,615 €
Annualised total costs (OPEX + depreciation)	**48,671,397 €**	**15,936,655 €**	**15,936,655 €**
Total annualised cost per unit marked	**0.00164 €**	**0.00054 €**	**0.00054 €**

2.2.6. Method of adding a security feature

2.2.6.1. Baseline and scope

Article 16 of the TPD states the need to have security features on all unit packets of tobacco products placed on the market, as a means to fight illicit trade. These packets must carry a tamper proof and irremovable security feature, composed of visible and invisible elements.

Member States that **already use tax stamps** as a fiscal marking may adjust the security features already implemented to comply with the requirements of Article 16 of the TPD, using a combination of visible and invisible elements, and **avoiding any major additional costs**.

The baseline that is considered for the costs calculation is the current situation in every MS regarding the unit packets of tobacco products. It is also important to highlight that the team assumptions need to be further analysed in WP3 by proceeding to a detailed analyse of each Member State regarding the actual security features in use.

	# MS	Unit packets	% Unit packets	Source
MS using affixed tax stamps that comply the TPD requirements	18	17,455,690,032	66.03%	(European Commission - Feasibility Study, 2015, p. 363)
MS using affixed tax stamps that could be required to update to be compliant with the TPD under options S1 and S3	5	4,848,802,787	18.34%	Team Operational experience
MS not using tax stamps	5	4,132,107,181	15.63%	(European Commission - Feasibility Study, 2015, p. 363)

NOTE:

- **MS that could be required to update their tax stamps to be compliant with the TPD under options S1 and S3–** There are Member States that may not be in

compliance with the TPD requirements with regards to their tax stamps and could be required to improve the security features on their tax stamps in order to comply with TPD requirements. It is assumed that five Member States will need to upgrade their security features. The number of unit packets is obtained by multiplying the average consumption of a Member State[17] by five.

- The following table gives an overview of the current situation about the use of tax stamps by Member States. The costs for applying the tax stamps are calculated pro rata the consumption of the five countries that do not have tax stamps yet.

	MS using affixed tax stamps	MS not using tax stamps
Austria		X
Belgium	X	
Bulgaria	X	
Croatia	X	
Cyprus		X
Czech Republic		X
Denmark	X	
Estonia	X	
Finland	X	
France	X	
Germany	X	
Greece	X	
Hungary	X	
Ireland	X	
Italy	X	
Latvia	X	
Lithuania	X	
Luxembourg	X	
Malta	X	
Netherlands	X	
Poland	X	
Portugal	X	
Romania	X	
Slovakia	X	
Slovenia	X	
Spain	X	
Sweden		X
United Kingdom		X

[17] Average consumption of a Member State = Total consumption of the 28 MS / 28

2.2.6.2. Assumptions

The assumptions used to calculate the costs for adding a security feature followed those used in the Feasibility Study:

- The definition presented on the cost analysis focuses only on how to add the security features to unit packets of tobacco products (OPEX).
- The cost to manufacture the security features (CAPEX) is out of scope for all three options, since the cost won't vary in any of the analysed parameters:
    - It is also considered that some Member States could manufacture the required security features for other Member States, if necessary.
- The costs to print or affix are calculated by multiplying the number of unit packets to be marked and the total costs to produce the security features.
- The total costs to print or affix the security features are represented by a cost range that contains everything necessary to print or affix and apply the security features – hardware, software, operating and related costs to apply the security feature in production lines.

Specific assumptions per option (S1), (S2) and (S3) are:

- Option (S1)
    - It is considered that 18 Member States have tax stamps complying with TPD;
    - It is assumed that tax stamps are applied to all types of tobacco products;
    - The 5 Member States that do not comply with the TPD must upgrade their tax stamps to be compliant, and it has been assumed that the upgrade would represent **50%** of the unitary cost (OPEX);
    - When affixing a security feature, two main affixing solutions are considered:
        - Dry label (a label without glue/ adhesive on it, suitable for application using high speed applicators such as those available on cigarette production lines); or
        - Self-adhesive labels (suitable for application using handheld label applicators or even by hand).
- Option (S2)
    - The costs are applicable to the 28 Member States.
    - It is assumed that all types of tobacco products will get a printed security features.
    - The cost analysis does not take into consideration the other types of security features that are already being used (i.e. tax stamps).
- Option (S3)
    - This option considers the optimal combination of security features that allows Member States to reach the lowest cost structure while meeting their obligations with regards to the TPD.

- The same assumptions than for S1 are applicable:
  - 18 Member States are using affixed security features that are compliant with the TPD;
  - 5 Member States are using affixed security features that are not yet compliant with the TPD and must be upgraded;
  - 5 Member States are not using affixed security features and must receive new security features.
- The optimal cost per type of tobacco products is obtained by taking the minimum unitary cost between of S1 and S2 options for each type of products.

	Optimal (minimum) unitary cost
Cigarettes - Unit Packets	AFFIXED (S1)
RYO unit packets	AFFIXED (S1)
Cigars (boxes) - Unit packets	AFFIXED (S1)
Pipe tobacco - Unit packets	PRINTED (S2)
Smokeless tobacco (chewing) - unit packets	PRINTED (S2)

Security features

	Current situation	S1	S2	S3
% Unit Packets	66.03% -MS with affixed tax stamp probably complying with TPD 18.34% - MS with affixed tax stamp probably not complying with TPD 15.63% - MS not using tax stamp	+18.34% - Not complying with TPD +15.63%- Not using tax stamp	100 % - Printing or integrating through a different method	+18.34% - Not complying with TPD +15.63% - Not using tax stamp

Methods of applying per tobacco product

	S1	S2	S3
Affixed - Dry label	• Cigarette packs = 100% • RYO = 100% • Cigars = 70%		• Cigarette packs = 100% • RYO = 100% • Cigars = 70%
Affixed - Self-adhesive label	• Cigars = 30% • Pipe tobacco = 100% • Smokeless chewing tobacco = 100% • Smokeless tobacco snus = 100%		• Cigars = 30% • Pipe tobacco = 100% • Smokeless chewing tobacco = 100% • Smokeless tobacco snus = 100%
Printing or integrating through a different method to all types of tobacco products		Printing or integrating through a different method to all types of tobacco products = 100%	

2.2.6.3. Figures, volumes and unitary costs

Unitary costs

	Minimum	Maximum	Selected Value	Source
Affixing - Dry label	0.0015 €	0.0030 €	**0.0023 €**	(European Commission - Feasibility Study, 2015, p. 323)
Affixing - Self-adhesive label	0.0030 €	0.0050 €	**0.0040 €**	(European Commission - Feasibility Study, 2015, p. 323)
Printing or integrating a security feature through a different method	0.0015 €	0.0042 €	**0.0029 €**	(European Commission - Feasibility Study, 2015, p. 323)

2.2.6.4. Results

The table below shows the results of the calculations for the three policy options that present the specific costs to affix, print or integrate through a different method, and use "Mixed solution" to add a security feature onto unit packets of tobacco products.

The costs to produce security features are calculated as the multiplication between the number of units to be marked and the unitary cost of these security features.

	S1	S2	S3
Security feature – cost	**14,912,513 €**	**75,344,310 €**	**14,889,183 €**

2.2.6.5. Summary

For security features, the optimal costs have been considered because it represents the minimal investment to bring the system in compliance with Article 16 of the TPD. The three options correspond to different burdens for the economic stakeholders. The highest cost calculated is for option (S2). Between option (S1) and option (S3), there is not much difference in terms of costs. However option (S3) offers the additional intangible benefit of giving Member States the flexibility of choosing their preferred method for applying the security features.

TOTAL	S1	S2	S3
CAPEX	- €	- €	- €
OPEX	14,912,513 €	75,344,310 €	14,889,183 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	14,912,513 €	75,344,310 €	14,889,183 €
Total annualised cost per unit marked	0.00050 €	0.00254 €	0.00050 €

2.3. Financial, sensitive and statistical analyses

This sub-section is comprised of three main parts:

- Financial analysis:

  - Verify the financial sustainability of the project.
  - Outline the yearly cash flows for the project life.
- Sensitivity analysis:
  - Identify the critical variables of the project and estimate the impact they have in the financial results.
  - Assess the effect of the critical variables on benefits and savings associated to the project.
  - Present the scenario analysis that studies the impact of variations taken by the tested variables.
  - Analyse the effect in the economic results of the potential of reducing illicit trade in the five policy options.
- Statistical analysis:
  - Estimate the evolution of the financial impact for uncertainties in the system.

2.3.1. Financial analysis

The financial analysis is included in the cost benefit analysis to compute the financial performance indicators. This analysis is carried out to:

- Assess the project profitability;
- Verify the financial sustainability of the project;
- Outline the yearly cash flows for the project life.

The financial analysis methodology is based on the Discounted Cash Flow (DCF) methodology (European Commission - DG REGIO, 2014) and it is composed of:

- The cash inflows and outflows;
- The financial discount rate;
- Timeline of the project.

The yearly cash flows are the difference between inflows and outflows for the timeline of the project. These cash flows were presented in the previous section. The inflows are the revenues, which are provided through a) revenue from increases in legal sales and b) other socio-economic benefits. The outflows are the costs that are divided into initial investment (CAPEX) and operating costs (OPEX).

The financial discount rate (FDR) is adopted in order to calculate the net present value of the future cash flows. This FDR reflects the cost of capital. For this particular analysis, the FDR has been estimated at 4% according to "Guide to Cost-Benefit Analysis of Investing Projects" (European Commission - DG REGIO, 2014).

The project timeline is the number of years for which forecasts of cash flows are considered. The choice of the timeline is relevant because it actively affects the net present value. For the purpose of this project, the timeline has been estimated at six years, according to the depreciation time presented in the literature (European Commission - Feasibility Study, 2015).

Year	Cash Flow	Inflows	Outflows
2018	-309.26 M€	- M€	309.26 M€
2019	205.74 M€	270.38 M€	64.64 M€
2020	697.62 M€	794.59 M€	96.97 M€
2021	1,757.08 M€	1,854.05 M€	96.97 M€
2022	2,281.30 M€	2,378.27 M€	96.97 M€
2023	2,539.04 M€	2,648.66 M€	109.62 M€
2024	2,659.40 M€	2,759.01 M€	99.61 M€
The inflows and outflows were obtained from the revenue-cost assessment			

Table 19: Financial cash flows

The financial net present value on investment is defined as the sum that results when all the discounted values of the expected yearly cash flows are added. The NPV is positive when the inflows exceed the outflows and they are discounted to the present, which add value to the investor. For this particular project the NPV is positive, which means that the project investment will bring financial benefits.

$$NPV = \frac{S_0}{(1+FDR)^0} + \frac{S_1}{(1+FDR)^1} + \cdots + \frac{S_n}{(1+FDR)^n} = 8{,}234.33\ Millions\ of\ €$$

The financial rate of return on investment is defined as the discount rate that produces a zero NPV. The calculations for this project reveal:

$$IRR = 176.58\%$$

The IRR rule states that if the IRR is greater than the minimum FDR (4%), then the project should be pursued. This affirmation confirms the assessment made by the analysis of the NPV.

2.3.2. Sensitivity analysis

The sensitivity analysis is required to deal with the uncertainty that could surround the investment project. It enables the identification of the "critical" variables of the project. Such variables are those whose variations (either positive or negative) have the largest impact on the financial performance of the project.

The tested variables are divided in two groups: revenue-related and cost-related. All the values were previously presented in the revenue and cost assessment. The sensitivity analysis uses the mean values of the EU, instead of using the country values (as used in the revenue and cost analysis). For the calculation of the sensitivity analysis the other socio-economic benefits are not considered in order to simplify the calculations.

Variable	Value
Revenue-based variables	
Total consumption	27,490 Millions of unit packets

Average price of unit packet	4.38€
Percentage of illicit trade	11.26%
Percentage of contraband reduction	30%
Percentage of counterfeit reduction	10%
Percentage of illicit whites reduction	10%
Percentage of illicit consumers that will purchase legal tobacco products	75.15%
Efficiency of the measure	Cumulative log-normal distribution
Cost-based variables	
CAPEX – Governance model	96.36 M€
CAPEX – Data storage model	19.01 M€
CAPEX – Allowed data carriers	167.59 M€
CAPEX – Allowed delays in reporting events	38.99 M€
CAPEX – Method of adding a security feature	No cost
OPEX – Governance model	26.94 M€
OPEX – Data storage model	7.29 M€
OPEX – Allowed data carriers	9.66 M€
OPEX – Allowed delays in reporting events	42.17 M€
OPEX – Method of adding a security feature	14.89 M€

Table 20: Tested variables

This analysis has been performed by varying one variable at a time and determining the effect of that change in the NPV. The variables are considered critical when their variation is higher than 1% of the value of NPV, and not critical when the variation is lower than 1%. In order to correctly perform this analysis, the tested variables must be independent and as disaggregated as possible.

Variable tested	Variation of the NPV due to a ±1% variation	Criticality judgement
Total consumption	1.10%	Critical
Average price of unit packet	1.10%	Not critical
Percentage of illicit trade	1.10%	Critical
Percentage of contraband reduction	0.87%	Not critical
Percentage of counterfeit reduction	0.04%	Not critical
Percentage of illicit whites reduction	0.19%	Not critical
Percentage of illicit consumers to legal	1.10%	Not critical
Efficiency of the measure	1.10%	Critical
CAPEX – Governance model	0.01%	Not critical
CAPEX – Data storage model	<0.01%	Not critical
CAPEX – Allowed data carriers	0.02%	Not critical

CAPEX – Allowed delays in reporting events	<0.01%	Not critical
CAPEX – Method of adding a security feature	N/A	Not applicable
OPEX – Governance model	0.02%	Not critical
OPEX – Data storage model	<0.01%	Not critical
OPEX – Allowed data carriers	0.01%	Not critical
OPEX – Allowed delays in reporting events	0.02%	Not critical
OPEX – Method of adding a security feature	0.01%	Not critical

Table 21: Sensitivity analysis

The sensitivity analysis reveals that the project's financial performance is not very sensitive to any change in the input variables, because the highest variation of the NPV corresponds to 1.1%. According to the analysis, the critical variables are:

- Total consumption;
- Average price of unit packet;
- Percentage of illicit trade;
- Percentage of illicit consumers to legal;
- Efficiency of the measure.

The sensitivity analysis is complemented with the calculation of the switching values. This is the value for which the tested variables produce a zero NPV. For the tested variables that residually contribute to the NPV, the switching value has been stated as not applicable.

Variable	Switching values	
Revenue-based variables		
Total consumption	Maximum decrease before NPV equals 0	91%
Average price of unit packet	Maximum decrease before NPV equals 0	Not applicable
Percentage of illicit trade	Maximum decrease before NPV equals 0	91%
Percentage of contraband reduction	Maximum decrease before NPV equals 0	Not applicable
Percentage of counterfeit reduction	Maximum decrease before NPV equals 0	Not applicable
Percentage of illicit whites reduction	Maximum decrease before NPV equals 0	Not applicable
Percentage of illicit consumers to legal	Maximum decrease before NPV equals 0	91%
Efficiency of the measure	Maximum decrease before NPV equals 0	91%
Cost-based variables		
CAPEX – Governance model	Minimum increase before NPV equals 0	8,600%
CAPEX – Data storage model	Minimum increase before NPV equals 0	Not applicable
CAPEX – Allowed data carriers	Minimum increase before NPV equals 0	5,250%
CAPEX – Allowed delays in reporting events	Minimum increase before NPV equals 0	Not applicable

CAPEX – Method of adding a security feature	Minimum increase before NPV equals 0	Not applicable
OPEX – Governance model	Minimum increase before NPV equals 0	6,400%
OPEX – Data storage model	Minimum increase before NPV equals 0	Not applicable
OPEX – Allowed data carriers	Minimum increase before NPV equals 0	Not applicable
OPEX – Allowed delays in reporting events	Minimum increase before NPV equals 0	4,100%
OPEX – Method of adding a security feature	Minimum increase before NPV equals 0	11,700%

Table 22: Switching values

Scenario analysis

Moreover, the sensitivity analysis is complemented with the scenario analysis, which studies the impact of combinations of values taken by the tested variables. As stated before, the tested variables are separated into two groups: revenue-based variables and cost-based variables. The combination of "optimistic" and "pessimistic" values of the critical variables is useful to build realistic scenarios.

For the purpose of this analysis, an impact of ±20% of the tested variables has been estimated.

		Revenue-related variables					
		Pessimistic		Current		Optimistic	
Cost-related variables	Pessimistic	NPV	1,588.19 M€	NPV	8,074.53 M€	NPV	25,113.50 M€
		IRR	54.48%	IRR	155.66%	IRR	333.85%
	Current	NPV	1,747.99 M€	NPV	8,234.33 M€	NPV	25,273.30 M€
		IRR	65.47%	IRR	176.58%	IRR	382.48%
	Optimistic	NPV	1,907.80 M€	NPV	8,394.13 M€	NPV	25,433.11 M€
		IRR	80.12%	IRR	208.01%	IRR	453.35%

Table 23: Sensitivity matrix

From the sensitivity matrix, two conclusions can be drawn:

- The project investment results are profitable for all the presented scenarios.
- The effect of the revenue-related variables is much stronger than the effect of the cost-related variables. This is evidenced by variations of one order of magnitude in the NPV for variations of ±20% in the revenue-related variables.

Effect of the policy options in the economic results

Finally, the sensitivity analysis is also reinforced respecting the effectiveness of the policy options in the economic results. To model the results per alternative policy option, we need to consider the 'Potential of reducing illicit trade' identified in each option.

This way, when an option presents the full potential of reducing illicit trade, it will be quantified as generating the baseline benefits. When an option presents a potential of

reducing illicit trade that ranks below optimal, the reduction in illicit trade will not reach the values defined for that baseline, generating benefits below the ones modelled before.

The way in which the 'Potential of reducing illicit trade' affects the benefits generated is through the specific reduction in contraband, counterfeit and illicit whites, as presented below:

	Potential of reducing illicit trade							
	87.5 to 100% = Baseline	**75 to 87.5%**	**62.5 to 75%**	**50 to 62.5%**	**37.5 to 50%**	**25 to 37.5%**	**12.5 to 25%**	**0 to 12.5%**
Contraband	30%	25%	20%	20%	15%	15%	10%	0%
Counterfeit	10%	10%	10%	5%	5%	2.5%	2.5%	0%
Illicit whites	10%	10%	10%	5%	5%	2.5%	2.5%	0%

Table 24: Policy options' effect in potential of reducing illicit trade

The coefficient of effectiveness for the measure is calculated as the combination of the scores of the different policy options (A-B-C-D-S), leading to an effectiveness of 0% when all the options obtain the lowest scores and 100% when they take the highest scores.

$$Effectiveness = \frac{A + B + C + D + S}{5}$$

The scores for the different policy options are presented in Chapter 4, and they are summarised in the table below:

Potential of reducing illicit trade				
(A) Governance model	**(B) Data storage model**	**(C) Allowed data carriers**	**(D) Allowed delays in reporting events**	**(S) Method of adding a security feature**
A1 – 100%	B1 – 100%	C1 – 50%	**D1 – 100%**	S1 – 75%
A2 – 100%	B2 – 25%	C2 – 100%	D2 – 75%	S2 – 50%
A3 – 100%	B3 – 25%	C3 – 100%	D3 – 50%	**S3 – 100%**
-	**B4 – 100%**	**C4 – 100%**	-	-
-		C5 – 50%	-	-

Table 25: Potential of reducing illicit trade for the studied alternatives

All the possible combination between options lead to 540 possibilities. This analysis analyses the effect of all the possible combinations in the economic revenues, showing them as a histogram.

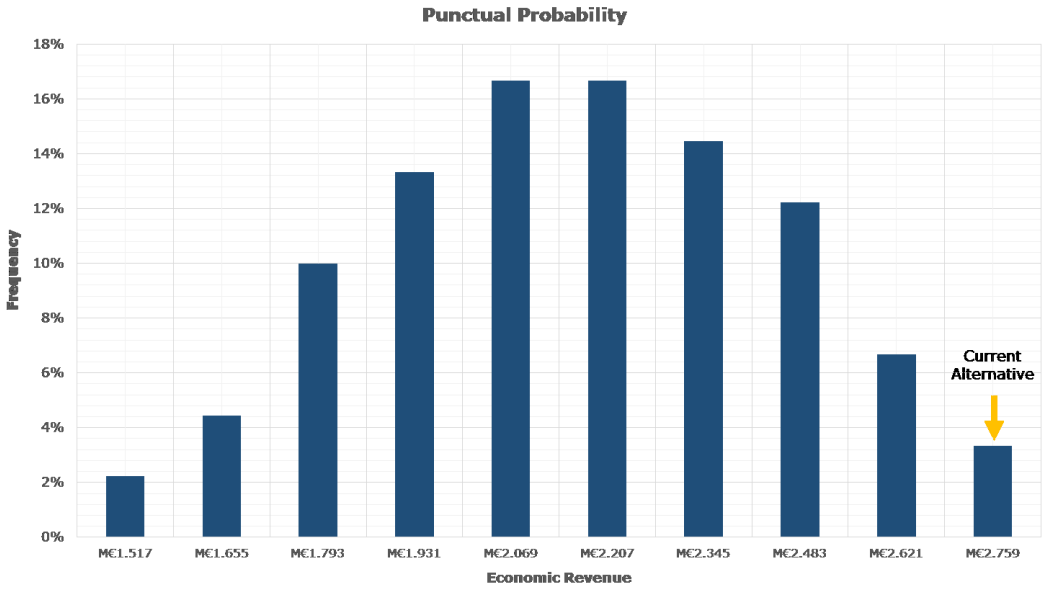


Figure 22: Probability density function of the economic revenue in base of the potential of reducing illicit trade

In conclusion, the selected option, corresponding to the combination (A3 – B4 – C4 – D1 – S3), provides the highest potential of reducing illicit trade. On the contrary, the combination that provides the lowest potential of reducing illicit trade will reduce the economic benefits down to 1,517 million euros.

2.3.3. Statistical analysis

The statistical analysis is carried out to estimate the evolution of the NPV when uncertainty is associated to the variables of the system. It numerically measures the probability of having a NPV lower than zero to quantitatively assess the profitability.

This analysis assigns a probability distribution to all the variables considered in the sensitivity analysis, defined in a precise range of values, to recalculate the expected values of financial performance indicators. Then, by means of a Monte Carlo simulation, the probability of distribution of the project's performance indicators (NPV, IRR) is calculated, repeated in 10,000 iterations.

An asymmetrical triangular probability distribution is applied to assess the behaviour of the variables under analysis:

- Revenue-related variables (-30%; +10%)
- Cost-related variables (-5%, +20%)

The assumed range of cost-related variables is based on the literature of probabilistic risk analysis (European Commission - DG REGIO, 2014) for investment projects. The assumed range of revenue-related variables is estimated to provide adverse scenarios that can compromise the financial performance of the project.

The analysis has been performed with specialised software for 10,000 simulations. The technique used is a Monte Carlo simulation (Raychaudhuri, 2008) (Kroese & Rubistein,

2012), which involves a random sampling method of each different probability distribution selected for the actual model set-up.

The result of the Monte Carlo drawings, expressed in terms of the probability distribution or cumulated probability of the NPV in the resulting interval of values, provides more comprehensive information about the risk profile of the project. The two figures below provide a visual example.

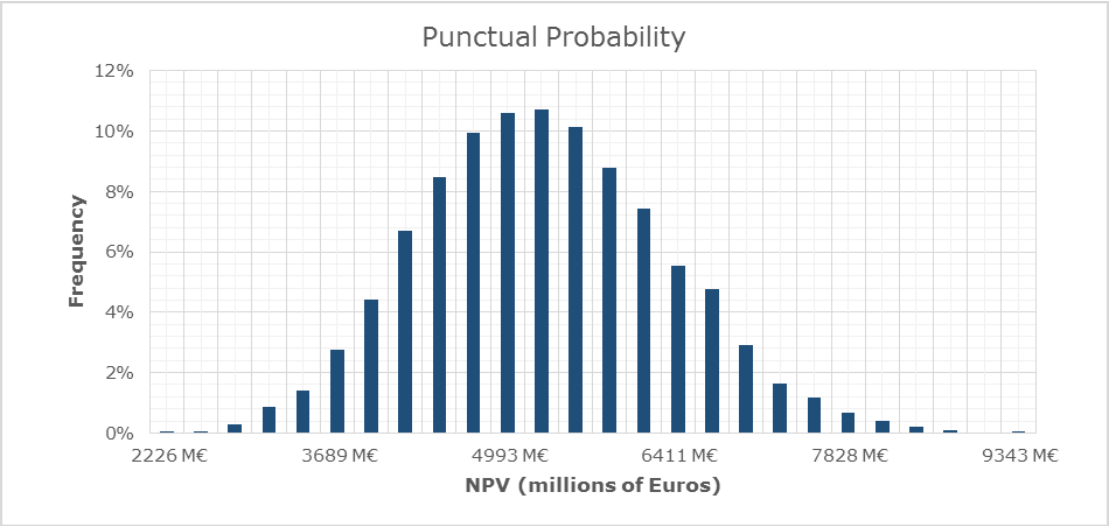


Figure 23: Probability density function of NPV

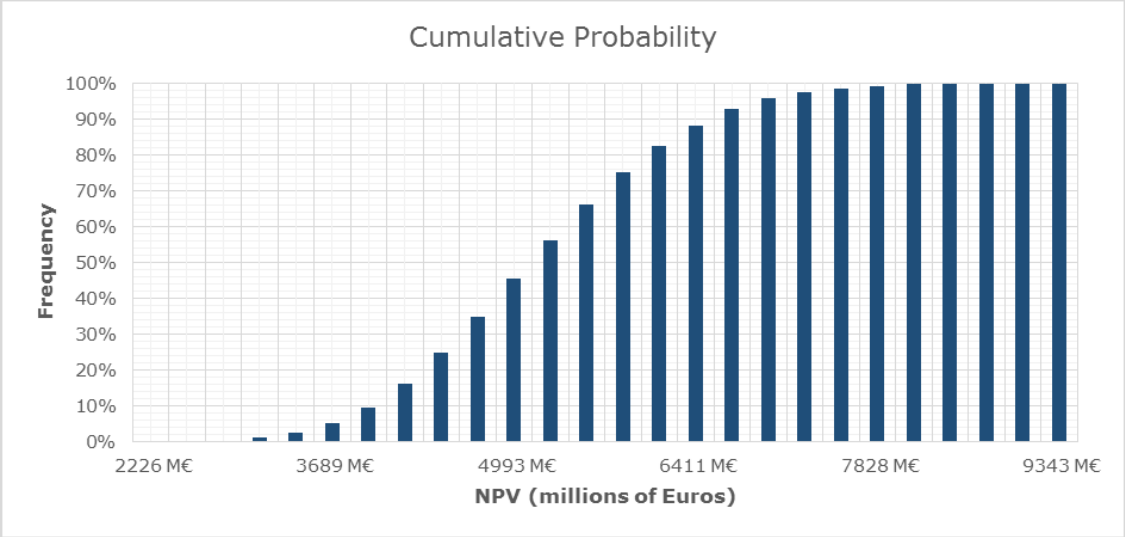


Figure 24: Cumulative probability of NPV

The cumulated probability curve assesses the project risk; for example, verifying whether the cumulative probability for a given value of NPV is higher or lower than a reference value that is considered to be critical.

The following table includes the representative metrics for the distribution of NPVs and IRRs obtained from the Monte Carlo simulation. Mean and median values are significantly lower than the base value as a consequence of the adverse distribution of the tested variables. Furthermore, the financial risk of the project is very low because none of the 10,000 simulations has provided a negative NPV.

Expected Values	Switching values	
Base	8,234.33 M€	176.58%
Mean	4,919.07 M€	122.31%
Median	4,888.99 M€	123.40%
Standard deviation	1,033.63 M€	16.86%
Minimum value	1,874.64 M€	66.27%
Central value	5,092.70 M€	125.92%
Maximum value	9,088.93 M€	176.06%
Probability of the NPV being lower than 0, or IRR lower than reference discount rate	0%	0%

Table 26: Sensitivity matrix

The results of the statistical analysis (Punctual and cumulative functions and table of expected values) assess the possibilities of the project to be profitable. The minimum value obtained for the most unfavourable situation is estimated at 1,874 M€ of NPV.

The mean value of 4,919 M€ is much lower than the base value as a consequence of the unfavourable distribution of the revenue-related and cost-related variables. Furthermore, the probability of the NPV being lower than 0, or IRR lower than the reference discount rate is 0%. This reduces the uncertainty of the economic profitability of the project.

Finally, after reviewing the financial analysis, the sensitivity analysis, and the probabilistic quantitative analysis, it can be confirmed that the economic implementation of the project is viable and will return profitability.

3. GLOSSARY AND TERMS OF REFERENCE

Acronym / Term	Definition
AI	Application Identifier
DSP	Data Storage Providers
EC	European Commission
EMCS	Excise Movement Control System; IT system provided by DG TAXUD to monitor in real-time the movement of excise goods under duty suspension in the EU – manufactured tobacco, alcohol and alcoholic beverages, and energy products
EO	Economic Operators
EPCIS	Electronic Product Code Information Services
ERP	Enterprise Resource Planning
EU	European Union
FCTC	Framework Convention Tobacco Control
GIAI	GS1 Global Individual Asset Identifier
GLN	GS1 Global Location Number
GTIN	GS1 Global Trade Item Number
MS	Member States
OTP	Other Tobacco Products
PM²	The project management methodology of the European Commission
RYO	Roll Your Own
SEED	System for Exchange of Excise Data; Database for companies to check the validity of an excise number
T&T	Tracking and Tracing
TM	Tobacco Manufacturer
TP	Tobacco Products
TPD	Tobacco Products Directive
UI	Unique Identifier
WHO	World Health Organisation

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