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REGULATORY SCRUTINY BOARD OPINION

Commission Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products

and

Commission Implementing Decision on technical standards for security features applied to tobacco products

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Brussels,
Ares(2017)

Opinion

Title: Impact assessment on the establishment of systems of traceability and security features for tobacco products

Overall opinion: POSITIVE

(A) Context

Illicit trade of tobacco products is reportedly widespread and growing in the EU. There are products on the market that do not comply with legislation and that evade taxes. A 2014 Tobacco Products Directive (TPD) provides for security features and systems to help trace tobacco products, a commitment also undertaken by the EU and its Member States under the WHO Framework Convention on Tobacco Control (FCTC). The European Commission is responsible for coming up with the technical specifications to establish and operate these systems.

This impact assessment covers two implementing acts, on traceability and on security features respectively. The report examines different alternatives to implement such systems. It considers both technical and governance aspects. It assesses their economic and social impacts, and compares costs and benefits of the different alternatives.

The report does not consider the delegated act on the provisions for the data storage contracts for the traceability system.

(B) Main considerations

The Board acknowledges extensive work to explore the different options and assess their likely impacts.

The Board gives a positive opinion, with a recommendation to further improve the report with respect to the following key aspects:

- (1) The reasons for discarding the option of a centralised database could be more clear.**
- (2) Assessments of costs and, especially, health benefits could be strengthened.**
- (3) The report could better describe how the proposed EU system would ensure effective global tracking and tracing of tobacco products.**
- (4) The report could better highlight how security features help make the proposed system innovative and robust to future technological developments.**

(C) Further considerations and adjustment recommendations

(1) Centralised database

A centralised database is presented as the most efficient option enjoying the widest support from Member States and NGOs. The report should further develop the technical, economic, operational and in particular legal arguments for discarding this option.

(2) Cost-benefit analysis and social dimension

The report should complement its assessment of costs and benefits of the proposed initiative in different ways. First, social impacts (notably health gains) should be more prominently described: it could refer to estimates from the impact assessment of the TPD and distinguish more clearly the specific benefits expected from the proposed system. Second, calculations should be updated with the latest available data (e.g. on smoking prevalence). Third, in terms of costs, the report should provide a more detailed breakdown of what the estimates include (e.g. in terms of role for the Commission).

(3) Interoperability

The report should clarify the limited requirements for interoperability between systems under the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products. It should explain how the proposed initiative will fit into the global tracking and tracing regime as defined in Article 8 of this Protocol. The addition of a flowchart and concrete examples of possible uses of the system will also contribute to clarifying the processes of storing and using data to tackle illicit trade in the EU and internationally. References to, and lessons from systems already developed by other countries, would also usefully inform the reader on the choices made for the EU system.

(4) Innovation and future-proofing

The report would benefit from further emphasising the steps taken to ensure that the system will support innovation and avoid rapid obsolescence, in particular concerning the proposed security features. To this end, the report could further describe the favoured non-prescriptive approach of setting minimum requirements and opting for open standards. It could also further highlight the potential benefits of being an early adopter and the first instance of regional implementation of such a system in view of exporting this model to other countries. In this context, the report could also make relevant references to other sectors subject to traceability systems and explain to what extent those may not be directly transposed to tobacco products.

(5) Scope and options

The report should present the reasons for not conducting an impact assessment on the delegated act on data storage contracts. It should also better justify the choice of options, especially when these deviate from those analysed in the underlying feasibility study.

Some more technical comments have been transmitted directly to the author DG.

(D) RSB scrutiny process

The lead DG may proceed.

Full title	Impact assessment on Implementing acts for the establishment of systems of traceability and security features for tobacco products under Articles 15(11) and 16(2) of the Tobacco Products Directive (TPD) 2014/40/EU
Reference number	2015/SANTE/694 and 2015/SANTE/696
Date of RSB meeting	27 April 2017

ANNEX 1 – PROCEDURAL STEPS – Consultation and External Expertise

**Commission Agenda planning*

The present initiative consists of two implementing acts and one delegated act as required under Articles 15(11), 15(12) and 16(2) of the TPD. These acts are included in the Commission's 'agenda planning' under reference numbers 2015/SANTE/694, 2015/SANTE/695 and 2015/SANTE/696.

1. Inception Impact Assessment

A key step in the implementation process was the publication of the Inception Impact Assessment (IIA)¹ in June 2016. This document considered a number of key questions for the design of a future tobacco traceability and security feature system.(such as what the future system's governance model should be, how the data storage should be arranged, how many data carriers for the Unique Identifier should be allowed; what the time delays in reporting events should be and how security features should best be added to unit packs). These questions, as well as the policy options it identified as potential answers, were used as key starting points for the in-depth evaluation carried out by both the Implementation Study (further details below) and the current Impact Assessment.

The table below sets out the key questions and policy options identified in the IIA.

¹ http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf

Traceability				Security feature
Who?	Where?	How?	When?	How?
(A) <i>Governance model</i>	(B) <i>Data storage location</i>	(C) <i>Allowed data carriers</i>	(D) <i>Allowed delays in reporting events</i>	(S) <i>Method of adding a security feature</i>
Option A1: Industry operated solution	Option B1: Centralised data storage	Option C1: System with a single data carrier	Option D1: Real-time (or limited delay) reports	Option S1: Affixing
Option A2: Third party operated solution	Option B2: Decentralised data storage	Option C2: System with a limited variety of data carriers	Option D2: Once daily reports	Option S2: Printing or integrating through a different method
Option A3: Mixed solution (industry and third party)	n/a	Option C3: Free system allowing any existing data carrier	Option D3: Once weekly reports	Option S3: Any method

Table 1: *Alternative policy options presented in the Inception Impact Assessment (p. 8)*

2. Consultation

Consultation Strategy

In July 2016, the Commission published a consultation strategy for the implementation of the EU traceability and security feature system.² This document sets out the evidence-based approach adopted by the Commission and the various consultation exercises foreseen throughout the implementation phase.

Commission Inter-Service Group

An Inter-Service Steering Group was set up and met on 29 April 2016, 15 September 2016, 20 December 2016, 15 February and 27 February 2017. In addition, written consultation of the ISG at various key points in the process was conducted. The Group was chaired by the Directorate-General for Health and Food Safety (SANTE) and meetings were attended by representatives of the Commission's Secretariat General (SG), Legal Service (SJ), DG Internal Market, Industry, Entrepreneurship and SMEs (GROW), DG Taxation and Customs Union (TAXUD); DG Informatics (DIGIT), the European Anti-Fraud Office (OLAF) and DG Trade

² https://ec.europa.eu/health/sites/health/files/tobacco/docs/2016_consultation_strategy_en.pdf

(TRADE). To gain additional expertise, there were additional contacts with the Commission's Joint Research Centre in Geel. In its meeting of 27 February 2017 the Group endorsed the draft Impact Assessment.

Consultation of Member States

Discussions with the Member States took place throughout the implementation phase. In particular the Commission has consulted experts from the national competent authorities of the Member States, notably via the Expert Subgroup on Traceability and Security Features which was established and met four times between December 2014 and December 2016.

The dates as well as summary records of these meetings are published at the following links:

Meeting of 10 December 2014:

http://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20141210_mi_en.pdf

Meeting of 03 July 2015:

http://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20150703_mi_en.pdf

Meeting of 22 June 2016:

http://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20160622_sr_en.pdf

Meeting of 16 December 2016:

http://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20161216_mi_en.pdf

Stakeholder Consultations

Targeted stakeholder consultation

A targeted stakeholder consultation was held from 7 May to 31 July 2015. The aim was to gather the views of the following stakeholders: manufacturers of finished tobacco products, wholesalers and distributors of finished tobacco products, providers of solutions for operating traceability and security features systems and governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade. In total 110 responses were received and published on the DG SANTE website, along with statistical analysis of the content of responses³.

The basis for the consultation was the Feasibility Study published on 7 May 2015.

A detailed summary of responses is presented in **Annex 2**.

Open public consultation

³ http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en.htm

An open public consultation from 29 July to 4 November 2016. The basis for the open public consultation were the policy options set out in the Inception Impact Assessment (IIA).⁴ The aim of the public consultation was to gain feedback regarding the relevance and impact that these policy options would have. In addition it aimed to:

- gain insight into the policy options capable of fulfilling the TPD requirements whilst at the same time imposing least burden on stakeholders concerned;
- gain realistic estimations of the financial impact of the envisaged policy options on stakeholders;
- gain insight into the impact of the envisaged policy options on SMEs;
- seek the feedback of consumers regarding aspects of particular relevance for them.

The target groups were: the general public/consumers of tobacco products, retailers of finished tobacco products, manufacturers of finished tobacco products, wholesalers and distributors of finished tobacco products, providers of solutions for operating traceability, security feature or data storage systems and governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade. In total 353 responses were received via the online tool. The responses of those who provided their consent will be published on the DG SANTE website, along with a statistical analysis of the content of responses.

A detailed summary of responses is presented in **Annex 3**.

Stakeholder workshops on the policy options

Two workshops were held in order to gather key input from affected stakeholders.

The first of these took place on 12 December 2016. Over 70 organisations attended this meeting, including manufacturers of finished tobacco products, solution providers, operators involved in the tobacco supply chain and NGOs. Invitations were issued to those organisations that had submitted contributions, either to the targeted stakeholder or public consultations, as well as to relevant organisations that had expressed interest in attending. Due to the high level of interest, priority was given to those organisations which were first in expressing interest, but a proportionate representation of groupings, including of stakeholders from the SME sector, was sought. In order to provide as broad an access as possible to the workshop, a web-streaming service was provided to all stakeholders whom it had not been possible to accommodate, or who had not been in a position to attend, in order to allow them to follow proceedings. On the basis of previous work carried out by the contractor in charge of the Implementation Study, the Commission circulated a presentation in advance of the workshop.

The second stakeholder workshop took place on 15 May 2017 and was again attended by over 70 organisations. Priority was given to those organisations which were first in expressing interest, but a proportionate representation of groupings, including of stakeholders from the SME sector, was sought and the proceedings were once again web-streamed. A presentation based on the previous work carried out by the contractor in charge of the Implementation Study, and setting out some of the options preliminarily preferred by the Commission, was circulated in advance of the workshop.

⁴ http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf/

Participants were given the opportunity to comment during the meeting and all participants, including those following via web-stream, could provide comments in writing up to one week following each workshop.

All comments were thoroughly reviewed by the Commission. In addition, the contractor was tasked with carrying out a detailed analysis with a view to making relevant revisions to its work, in particular to its draft interim report II, the main findings of which are presented in **Annexes 4 and 5** of this report.

Summary records of the stakeholder workshops are published at the following links:

Workshop of 12 December 2016:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20161212_sr_en_2.pdf

Workshop of 15 May 2017:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20170515_sr_en.pdf

3. External Expertise

Feasibility Study

Prior to the TPD in 2013, in the context of tender n° EAHC/2013/Health/11, Eurogroup Consulting Portugal – Consultoria em gestão, LDA, Eurogroup Consulting was engaged as an external contractor to the Commission to carry out a Feasibility Study regarding EU systems for tracking and tracing of tobacco products and for security features.

The study, published in 2015, concluded that full traceability of EU tobacco products is achievable.⁵ It also confirmed that there are many solutions for security features that meet the requirements of the TPD.

The Feasibility Study provided a large amount of information and in particular presented four potential solutions for traceability and four for security features.

The four traceability options were based either on an industry-led, third party-led or mixed governance model:

- Option 1: an industry-operated solution, with direct product marking carried out by tobacco manufacturers; manufactures are free to select an independent data storage provider; standards for the system are laid down by the Commission via secondary legislation.
- Option 2: a solution operated by a third party responsible for the product marking process on the production line; the system operates with one central independent data storage provider; standards for the system are laid down by the Commission via secondary legislation.
- Option 3: a mixed governance model with each Member State selects between Option 1 and 2 regarding the entity responsible for product marking (manufacture or independent solution provider); the system operates with multiple independent data storage providers; minimum standards (for interoperability) are laid down by the Commission via secondary legislation.
- Option 4: a unique identifier is integrated with a security feature and affixed in the same process as a security feature; the system operates with (a) independent data storage provider(s).

Each of the proposed traceability solutions proposed by the Feasibility Study reflects the basic requirements set out under Articles 15 and 16 of the TPD, i.e. a unique identifier must be affixed to a unit packet at the manufacturing site, while information on a unique identifier, along with additional information required by Article 15(2) (which are generated during production and distribution of tobacco products) must be saved at an independent data storage facility.

Regarding the solutions for security features, each option presented by the Feasibility Study includes several levels of protecting features: overt, semi-covert, covert and forensic. On the basis of various available technologies the Feasibility Study proposed the following four options:

- Option 1: a security feature using similar authentication technologies to a tax stamp;

⁵ http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

- Option 2: reduced semi-covert elements as compared to Option 1, where the co-presence of a unique identifier is regarded as equivalent to the semi-covert level of protection;
- Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection;
- Option 4: a security feature is integrated with a unique identifier (see Option 4 for traceability).

The Feasibility Study concluded that no matter which traceability and security feature option is selected, the benefits clearly outweigh the costs from both economic and social perspectives. However, it also recognised that the above options may vary in terms of the likelihood of achieving the full benefits expected from the introduction of traceability and security features.

The information included in the Feasibility Study provided the basis for subsequent inquiries and notably informed the policy options outlined in the Inception Impact Assessment.⁶ In addition the findings of the Feasibility Study were further analysed in the context of the Implementation Study.

Implementation Study

In June 2016, a consortium of Everis Consulting and PWC was engaged by the Commission to carry out an Implementation Study on the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products.

The purpose of the study was to provide the Commission with targeted assistance and technical input in the preparation of its implementation tasks.

The key tasks of this study consisted of:

- providing an in-depth analysis of the findings of the Feasibility Study and completing the technical knowledge base where required (under Work Package 1);
- proposing a concept for an optimal system for tracking and tracing, including the third party data storage (under Work Package 2);
- specification of proposed technical requirements (under Work Package 3);

Key input for the present Impact Assessment was delivered under **Work Package 2** of the Implementation Study. This included: (a) refinement and overall evaluation of the policy options put forward in the Inception Impact Assessment and (b) the cost-benefit analysis of the policy options.

The policy options in question were evaluated against a set of defined selection criteria, distributed in two groups:

- Primary requirements⁷:
 - Full compliance with Articles 15 and 16 of the TPD and Article 8 of the FCTC Protocol;

⁶ http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf

⁷ Options that did not fulfil these requirements were discarded in the final selection even if they scored higher than the other options for the secondary requirements.

- Secondary requirements⁸:
 - Technical feasibility;
 - Interoperability (with key users' and other companies' systems);
 - Ease of operation;
 - System integrity;
 - System security;
 - Potential of reducing illicit trade;
 - Burden for economic stakeholders;
 - Burden for public authorities.

The above selection criteria were applied to all policy options in order to enable a uniform comparison to be performed and, ultimately, preferred policy options for the creation of an optimal high level solution to be selected. The evaluation methodology also defined an approach for weighting the eight secondary requirement selection criteria, based on their expected impact on stakeholders.

In addition, evaluation criteria specific to each policy option were defined for each selection criterion. The final score of an option was obtained by assessing the evaluation criteria, adding them to get the score of the selection criteria, applying the weighting and calculating the weighted average.

The evaluations conducted by the contractor were informed and supplemented by the review and comments received at a series of key meetings organised in December 2016 with **Member State** representatives, **independent experts**, **stakeholders** (including manufacturers, solution providers, operators, retailers, NGOs and standardisation bodies) and the **Commission's Inter-Service Group**. The feedback received were taken into account and the description, evaluation and final assessment of the various policy options were refined accordingly.

The results of the assessment of the policy options carried out in Work Package 2 led to the selection by the Implementation Study of a set of **preferred policy options** for the creation of an optimal high level solution. These are outlined in the table below.

A summary of the key findings of Work Package 2 of the Implementation Study is presented in Annexes 4 and 5.

⁸ The objective was to select the option that fulfilled the selection criteria in the most optimal way.

Tracking and tracing			
Who?	Where?	How?	When?
(A) Governance model	(B) Data storage model	(C) Allowed data carriers	(D) Allowed delays in reporting events
(A1) Industry operated solution	(B1) Centralised model	(C1) System with a single data carrier for all identification levels	(D1) Near real-time reports
(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
(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
-	(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 2: Work Package 2, Implementation Study: Preferred policy options

ANNEX 2 – SUMMARY OF THE STAKEHOLDER COMMENTS

in the context of the **targeted stakeholder consultation** on the implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU

CONTENTS

1. Member States and other governmental organisations.....	2
2. NGOs / Organised civil society.....	4
3. Manufacturers of finished tobacco products	6
4. Operators involved in the supply chain of finished tobacco products (excluding retail)	9
5. Solutions providers.....	11
6. Other organisations.....	13

1. Member States and other governmental organisations

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, governmental organisations prefer Option 2 (single EU-wide solution), justified by the threats to public health and the evidence of previous complicity in illicit trade by the tobacco industry and with possible future involvement of multiple solutions providers so as to ensure completion. In particular, they recommend an accreditation system that is applicable to all types of tobacco production and appropriately detailed so as to ensure compatibility and interoperability while not excluding too many solutions providers unable to live up to the requirements. Some leeway should be given to national authorities in order not to overburden SMEs and economic operators involved in the tobacco trade should not be excluded from implementation.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, governmental organisations prefer Option 1 (a security feature using authentication technologies similar to a modern tax stamp), albeit classified slightly above 'neutral'. Concerns were raised regarding all four stamp-based options in relation to the risks of counterfeiting, the high supervision costs and the risk that visible security features might induce consumers to mistake harmful tobacco products for 'quality' products. They also recommended that the security feature should be multi-layered and that each MS is allowed to choose the most appropriate solution based on the risks in their illicit market and with a specification by the EC.

Benefit analysis

Among governmental organisations, the main reasons for disagreement are the vague definition of the benefits, the assumption that there is a consistent structure of the illicit market across MS and the unrealistic assumption of price elasticity.

Cost analysis

The opinions of governmental organisations with regards to the cost analysis tend to swing between 'Neither agree nor disagree' or 'No opinion'. When disagreeing, they mainly point to the unconvincing calculation basis and the lack of consideration for the costs of integrating the system with the companies accounting package.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, the majority of governmental organisations support Option A (a single standard provided by a relevant standardization body), to be preferably based on GS1, especially on the form of a serialised GTIN.

In relation to data carriers to be used for a serialized unique identifier, most of governmental organisations call for Option A (solution based on the minimum technical requirement that allow for the use of multiple data carriers) operating both with machine and human readable codes.

In relation to the physical placement of a serialized unique identifier, they have no opinion but some of them prefer the placement of the identifier after the pack is folded/assembled and filled with products in order to avoid diversions of identified packs during the production process and contain the wastage of packs (and codes) which is higher before final assembly. In order not to overburden SMEs, they also suggest to allow them to use 'stickers' on small batches of tobacco products following the requirements for affixation set out by national authorities.

In relation to entities responsible for each step of the application of serialized unique identifiers, governmental organisations have different responses for each phase of the process: 1) an independent third party should be responsible for generating identifiers; 2) an economic operator involved in the tobacco trade supervised by the authorities should be charged with marking products with identifiers, scanning products upon dispatch from manufacturer's/ importer's warehouse; 3) an economic operator involved in the tobacco trade supervised by the third party auditor should be responsible for the aggregation of products; 4) the other phases (i.e. verifying if products are properly marked, scanning products upon receipt at and upon dispatch from distributor's/ wholesaler's premises, scanning products) should be entrusted to an economic operator involved in the tobacco trade either supervised by the authorities or by a third party auditor.

In relation to the method of putting the security feature on the pack/ tin / pouch / item, they support Option C (a security feature is printed), although they believe that it should be for each MS to decide the type, format and content of the security feature on the basis of EU specification.

In relation to the implementation of the independent data storage, responses are divided between a single centralised storage for all operators and an accreditation or similar system for multiple interoperable storages.

In relation to the development of reporting and query tools, governmental organisations do not have a clear preference as to who should develop such tools.

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, most of governmental organisations do not have any opinion, although they recommend that consumers shall not be granted access to the T&T movement data but simply to data concerning the authenticity of the product.

Lastly, they expressed concerns about the outcome of and the responsibility for the decision making process (i.e. the Commission or each MS), the effectiveness of sanctions, the possibility of allowing overseas marking (i.e. in the country of manufacture), the need to take into account the different nature and supply chains of the various tobacco products.

2. NGOs / Organised civil society

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, the NGOs prefer Option 2 (an EU-wide third party-operated solution) with a view to facilitating exchange of information within the EU. In order to avoid the risk of monopoly, they recommend a T&T system supplied by several providers, even though this might increase the complexity of the system. They also raised concerns about the feasibility of this solution within May 2019 because of the scale of such an option across all phases of the supply chain in the EU. They also stress the interoperability deficiencies of Option 3.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, the preferred solution for NGOs is Option 1 (a security feature using authentication technologies similar to a modern tax stamp), albeit classified between 'somewhat inappropriate' and 'neutral'. Affixed security features are seen as inappropriate for a number of reasons: they authenticate the marker itself rather than the pack, they are easily removable and, if combined with T&T identifier, there might be problem with the placement of the stamps on the production lines. They also fear that visible security features might induce consumers to mistake harmful tobacco products for 'quality' products. NGOs also recommend the combination of over, cover and forensic features.

Benefit analysis

Despite having no opinion on this matter, NGOs stress that the vast majority of EU illicit trade is non-EU sourced, thereby not affected by EU measures. They found that there might be added benefits if interventions are based not only on intelligence and risk analysis but also on a random sample. This will lead to better information about products diversions and thereby facilitate large scale enforcement investigations and more efficient allocation of investigation resources. To achieve this, three crucial factors are needed: interoperability also with extra-EU administrations to be based on a global technical standard, sufficient resources to detect counterfeit markings, persuasion of the general public to help authorities by reporting suspect products.

Cost analysis

The majority of NGOs has no opinion regarding the cost analysis and no particular concerns are expressed.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, NGOs have no opinion concerning this matter.

In relation to data carriers to be used for a serialized unique identifier, most of NGOs prefer Option A (solution based on a single data carrier), preferably through 2D data carriers, a completely independent standardization body and both machine and human readable codes.

In relation to the physical placement of a serialized unique identifier, they expressed no clear preference but pointed out that for cigars packed by hand in wooden or cardboard boxes, it is necessary to apply the unique code via label as well as to define the date and place of manufacturing and apply the identifier when the packs are finished with health warning labels, tax stamps and EAN-code label.

In relation to entities responsible for each step of the application of serialized unique identifiers, all steps should be entrusted to an economic operator involved in the tobacco trade supervised by the authorities, except for products aggregation, to be entrusted to an economic operator supervised by the third party auditor.

In relation to the method of putting the security feature on the pack/ tin / pouch / item and to the implementation of the independent data storage, most of NGOs have no opinion on these matters.

In relation to the development of reporting and query tools, they prefer to have the provider of data storage services developing reporting and query tools and suggest the creation of a technical sub-group of the competent enforcement authorities of each MS to design the way to implement such tools.

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, most of NGOs have a favourable opinion considering that such empowerment would build consumers' trust to buy authentic products and authorities will have an additional check at the end of the supply chain, even though there are also concerns that identifiers might be mistaken for quality marks.

Lastly, they highlighted the need burdens and benefits of the system so as not to overburden small producers.

3. Manufacturers of finished tobacco products

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, the great majority of manufacturers indicated Option 1 (industry-operated solution) as their preferred option and highlighted concerns regarding the other options. In particular, they envisaged that Option 2 (single EU-wide solution) might require that a high number of unique identifiers be stored and administered within a single EU-wide repository as well as run the risk of monopolization of T&T of tobacco products in the EU into the hands of a single solution provider. As to Option 3 (national blends), their main concerns included the lack of homogeneity in the manufacturing environment, (with potentially multiple solutions running simultaneously, each operated by a different provider) and the need of enhanced coordination between national databases with regards to the data structure and methodology for collecting data on cross-border movements. Moreover, they found that Option 4 (pre-printed unique identifier), besides showing the same lack of homogeneity as Option 3, would entail difficulties in the scanning of the unique identifier during the production process if the identifier is going to be located on the top/side of a pack, not to mention the high risk of loss, theft, damage and tampering of pre-printed unique identifiers and the need for each manufacturer to adapt its production to the different requirements for fiscal stamps in each Member State. Lastly, it was pointed out that since all options but 1 would require public tenders to be implemented they would hardly be finalised before the implementation deadline in May 2019.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, according to the manufacturers' responses Option 4 (combined traceability/security features) is the preferred solution, even though the other options were not considered as totally inappropriate. The major concern related to all four proposed options is that they are paper-based, thereby unable to protect the whole pack from circumvention. Plus, there is a high risk for the paper-based security feature being lost or stolen and then applied to illegal products as well as reduced flexibility for Member States which do not have tax stamps or are planning to discontinue them. As recommendations for implementation, the manufacturers called for enhanced flexibility through adaptation of the security features to the specific materials and packaging of different tobacco products, fostering modern technologies and allowing choice and adaptation of security features according to counterfeiting trends.

Benefit analysis

Most of the manufacturers disagree with the benefit analysis and listed at least three major assumptions that seem to be inaccurate or inconsistent: 1) there is no actual price elasticity justifying reduction of consumption since unaware illicit buyers normally already pay the regular price; 2) the vast majority of EU illicit trade is non-EU sourced, thereby not affected by EU measures; 3) the prevented illicit volume will not realistically return to the duty-paid market, as many consumers will recourse to other cheap tobacco products (e.g. raw tobacco).

Cost analysis

On the manufacturers' side, many factors were found to have been disregarded in the cost analysis including the investments already made in development and implementation, software, database or data transfer developments and operations, facilities exporting into the EU, fine-cut, pipe, snuffing, chewing or waterpipe tobacco, integration of T&T with other systems, re-configuration of the distribution lines and additional equipment. Further concerns were expressed regarding the lack of differentiation between single shop retailers and retailers operating multiple shops, the complexity and timeframe for implementation of the solution, the poor performance of the paper-based solution in terms of effectiveness and cost-efficiency, the relatively greater burden of compliance put on smaller suppliers.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, manufacturers expressed a clear preference for Option A (a single standard provided by a relevant standardization body), to be based on the GS1 standard. In particular, they pointed to the insertion of a security element to ensure integrity of the data stored as well as to compliance with international standards (such as GS1) to ensure compatibility with various data carriers. They also expressed concerns about the size of the identifier and the time for placing the data on the identifier, as the intended shipment route cannot be declared at the time of manufacture.

In relation to data carriers to be used for a serialized unique identifier, the vast majority of the manufacturers selected Option B (solution based on the minimum technical requirements that allow for the use of multiple data carriers) based on GS1 standard and varied formats of data carriers depending on the packaging level (so as to not sacrifice readability in case of high manufacturing speeds) and operating with both machine and human readable codes.

In relation to the physical placement of a serialized unique identifier, most of manufacturers preferred the physical placement of the serialized unique identifier at the latest possible stage (i.e. after the pack is assembled and filled with products) with a view to limiting the number of damaged/destroyed unique identifiers to be discarded. Moreover, they claimed that the identifier should be placed on the top or bottom of packs so that it can be read and aggregated into a higher packaging unit.

In relation to entities responsible for each step of the application of serialized unique identifiers, most of manufacturers consider best to have an "Economic operator involved in the tobacco trade supervised by the authorities" responsible for generating identifiers and an "Economic operator involved in the tobacco trade without specific supervision" responsible for affixation, verification, scanning and aggregation tasks.

In relation to the method of putting the security feature on the pack/ tin / pouch / item, despite the absence of a clear preferred choice, the manufacturers showed a tendency towards Option C (printed security feature) relying on three visible elements (the pack itself, the machine and the human readable identifiers) and one invisible element (e.g. fingerprint, invisible inks, taggants, etc.), with no need for additional paper stamps for authentication.

In relation to the implementation of the independent data storage, the majority of manufacturers selected Option B (accreditation or similar system for multiple interoperable storages), preferably to be organised per country rather than centralized at EU-level.

In relation to the development of reporting and query tools, there is no clear preference among manufacturers between Option A (provider of solutions to collect the data from the manufacturing and distribution chain) and Option B (provider of data storage services). Nevertheless, they pointed out that the databases need to be GS1 EPCIS standard compliant so as to foster security and confidentiality.

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, manufacturers expressed a favourable opinion based on positive experience in other industries and claimed the possibility to increase consumers' awareness about illicit trade.

Lastly, manufacturers provided additional comments on the subject of consultation highlighting that, since there is no perfect solution to tackle illicit trade in tobacco products, it is crucial to encourage collaboration, share knowledge and promote open technical standards.

4. Operators involved in the supply chain of finished tobacco products (excluding retail)

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, the majority of respondents in this category indicated Option 1 (industry-operated solution). Concerns were raised with respect to Option 2 and its anti-competitive implications, the need for complex data storage requirements and the unlikely implementation within the May 2019 deadline. There were also concerns about the integration of the future T&T system with existing information systems related to manufacturing order, invoicing and payments. Most of suppliers also criticized the options relying on national databases (Options 3 and 4) for being too unrealistic, given the difficulty to implement 28 identical databases (one per MS) and to develop a software to recreate the cross-border events from these databases. As to the export of products, they underlined the fact that if specific identifiers for export or export stamps are used this would create problems for export markets that already have in place tax stamps. A unique EU-wide system was also indicated as a means to support growth and development and reduce burdens for wholesalers and distributors.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, despite most respondents preferring Option 3 (fingerprinting), they also considered it as 'somewhat inappropriate' since all four solutions including fingerprinting are paper-based and thereby can be counterfeited. Concerns were also raised about size and placement of the stamps. Lastly, they called for enhanced flexibility of the security feature according to different types of tobacco products.

Benefit analysis

The majority of operators involved in the supply chain disagree with the benefit analysis for disregarding potential prices increases arising from annual implementation costs and the consequent decrease of legal sales.

Cost analysis

The majority of operators involved in the supply chain disagree with the benefit analysis for disregarding differences between wholesale sectors of each MS and adaptation costs of MRP, accounting, invoicing and warehousing systems. There are also specific concerns regarding each type of operator. Large distributors and wholesalers highlight that the analysis only considers highly manual operations and not also automation (and its related investments in centralized facilities and the increased HR operational costs in relation to cases of insufficient code readability compliance rate) and inventories. Regarding vending machines and mobile forces, one of the concerns is the wrongly assessed vending machine service vans universe and the biased figure of delivery units of mobile sales force deriving from such wrongly assessed universe.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, most respondents in this category indicate Option A (a single standard provided by a relevant standardization body) to be based on the GS1 standard and standardized at EU level.

In relation to data carriers to be used for a serialized unique identifier, some operators selected option A (solution based on a single data carrier) claiming that the use of multiple data carriers would increase equipment costs and time required for each operation. They also support the use of both machine and human readable codes, where the latter are intended for use when the machine readable code is damaged.

In relation to the physical placement of a serialized unique identifier, most of operators prefer the physical placement of the serialized unique identifier at the latest possible stage (i.e. after the pack is assembled and filled with products). In particular, they claimed that it is indifferent where the identifier is placed at pack level, whereas at carton level there should be one identifier per side with a minimum of two, at master case level there should be one identifier per side and a minimum of two labels in two opposite vertical faces of the boxes, at pallet level there should be two labels in each one of the larger sides.

In relation to entities responsible for each step of the application of serialized unique identifiers, the majority of operators defended that all tasks should be conducted by an "Economic operator involved in the tobacco trade supervised by the authorities".

In relation to the method of putting the security feature on the pack/ tin / pouch / item, they indicated Option C (A security feature is printed) and Option D (a security feature is put on the pack/ tin/ pouch / item through a different method, so as to avoid affixed features falling off or being tampered).

In relation to the implementation of the independent data storage, they prefer a single centralised storage with a view to concentrating the content of an order in only one message and putting reduced message storing burdens on distributors.

In relation to the development of reporting and query tools, no clear preference was expressed between Option A (provider of solutions to collect the data from the manufacturing and distribution chain) and Option B (provider of data storage services).

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, also operators have a favourable opinion even though they doubt about the time needed to implement these tools.

Lastly, they provided additional comments claiming the lack of attention paid to wholesalers and distributors in the Feasibility Study and called for a financially affordable system based on equitable sharing of costs.

5. Solutions providers

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, the solution providers prefer Option 1 (industry-operated solution) as Option 2 (single EU-wide solution) is believed to be not technically and organizationally feasible due the complex data storage requirements as well as the high costs of adaptation of production lines and consequential risk of closure of smaller manufacturers. Moreover, also solutions providers criticized the monopolistic implications of Option 2, calling for the prescription of interoperability and common standards to expand the selection process to multiple independent vendors. Option 3 (national blends) prevents economies of scale and collaboration between MS and obstacles exchange of information, whereas Option 4 (pre-printed unique identifier) lacks authentication efficiency and requires large financial burden and implementation time.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, the majority of solution providers prefer Option 4 (combined traceability/security features) to be based on fingerprinting as a new technology having minor impact on the production process and able to avoid the counterfeiting risks of paper-based solutions. They also recommend the combination of over, semi-covert and cover security features as a means to curb counterfeiting and to maintain flexible requirements in order to ensure interoperability and competition between individual solution providers.

Benefit analysis

The solution providers do not have a clear position with regards to the benefit analysis as they assume that the benefits generated would be the same for all options and maintain that regulatory interference without breaking the alliance between consumers and illicit suppliers would only result in rising prices and thereby increased demand on the illegal market.

Cost analysis

Most of solution providers disagree with the cost analysis, since if Option 1 is preferred for T&T the costs analysis should not take into account previous investments of tobacco manufacturers in this direction. As to Option 4, the analysis seems to neglect the costs linked to the use of tax stamps (e.g. transportation, storage, risk management of counterfeit, etc.) while duplicating the costs already taken for fiscal purposes by those MS that already have security features on their tax stamps.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, most of the solution providers prefer Option (a single standard provided by a relevant standardization body), to be based on the GS1 standard. In particular, they called for enhanced flexibility and reduced complexity of the standardisation process to be achieved through separation of data included in the identifiers from data linked to the identifier by a relation in the database.

In relation to data carriers to be used for a serialized unique identifier, most of solution providers selected Option A (solution based on a single data carrier), possibly through 2D data carriers and RFID tags which enable the scanning of large volumes of tobacco products simultaneously. In order to reduce the high costs of applying the RFID chip on the package, they proposed that such a chip is integrated in the package by the manufacturers. The system should preferably operate both with machine and human readable codes, as the former would allow for the aggregation process, verifications from the authorities and smartphone scanning from the consumers and the latter would solve many technical problems of the system.

In relation to the physical placement of a serialized unique identifier, they supported the placement of the identifier once the pack has been assembled and filled in order to avoid manipulations and streamline operations.

In relation to entities responsible for each step of the application of serialized unique identifiers, there is no prevailing position. However, they provided recommendations regarding the implementation of the TPD, including a strong control of serialization on production with a view to build one point of almost certain base of data, the marking of export products so as to avoid export fraud of taxes and inclusion of supervision among the functions of the T&T system.

In relation to the method of putting the security feature on the pack/ tin / pouch / item, there is no clear preference among solutions providers since some of them support the placement of the identifier on tax stamps produced by an independent provider so as to ensure accountability of product quantity, some others recommend the use of printed solutions such as digital fingerprint so as to avoid modifications of the speed and manufacturing processes.

In relation to the implementation of the independent data storage, solutions providers prefer an accreditation or similar system for multiple interoperable storages. If organised per manufacturer, the databases should be implemented through the use of different storages interoperable among different operators in the supply chain, each of which should provide data to be reversed into a single efficient database managed by the data storing company for each MS and then included into the official repository accessible by the authorities. If organised per country, one independent data storage should be placed in each MS and the supplier should be selected by the governments.

In relation to the development of reporting and query tools, providers of solutions consider that reporting and query tools could be provided by both providers of solutions and providers of data storage services through the delivery of preventive IT Systems combining multiple data sources (both structured and unstructured) to reveal illicit trade patterns and predict the likelihood of criminal events.

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, most of providers of solutions agree with the individual consumers' verification empowerment expressing similar views to those of the other stakeholders.

Lastly, providers of solutions recommended that any proposed T&T system is based on unique identification, interoperability, collaboration between industries and organizations and combination of repressive and preventive measures.

6. Other organisations

Options for Tracking and Tracing ("T&T") proposed in the Feasibility Study

In relation to the appropriateness of each option for the T&T system set out in the Feasibility Study, the solution preferred is Option 1 (industry-operated solution). Option 2 is criticized for its monopolistic implications and concerns were also raised as to the timing of the implementation of the TPD in relation to Options 2, 3 and 4.

Options for Security Features proposed in the Feasibility Study

In relation to the appropriateness of each option for security features set out in the Feasibility Study, respondents in this category prefer Option 3 (fingerprinting technology used for the semi-cover and covert levels of protection), albeit still considered as below a 'somewhat inappropriate' level. Fingerprinting allows avoiding the risks of paper-stamps glued onto a pack. The responsibility to secure and authenticate the products should lie with the manufacturers.

Benefit analysis

The majority of 'other' organisations disagree with the benefit analysis pointing out the impossibility to find the most effective option as all four options proposed will give the same result and the need to combine the system with a focus on public awareness, enhanced field inspection and control and strengthened law enforcement.

Cost analysis

They disagree with the cost analysis for the following reasons. Option 1 disregards the initial development costs for each supplier and the previous investments made by manufacturers that already have T&T systems. The same applies to Options 2, 3 and 4. Option 2 also disregards the operational costs to be faced by manufacturers to fix technical issues. In Option 4 the costs for adjusting the manufacturing equipment are underestimated. All four options do not take into account the small manufacturers in the cost analysis.

Additional questions

In relation to the modalities for the generation of a serialised unique identifier, the majority of 'other' organisations support Option A (a single standard provided by the relevant standardization body), to be based on GS1 data carriers.

In relation to data carriers to be used for a serialized unique identifier, there is a slight preference for Option B (solution based on the minimum technical requirements that allow for the use of multiple data carriers) in order to foster flexibility in the serialization process. Plus, the GS1 standard will lead to greater homogeneity with other tobacco operators and industries and contain the impact on the supply chain. They believe that the system should operate through both machine and human readable codes.

In relation to the physical placement of a serialized unique identifier, they indicated placement after assembly and fill as their preferred option and claimed that identifiers should be flexible in order not to obstacle aggregation and that identifiers should be applied after cellophane packaging so that it serves as a protection of the identifiers.

In relation to entities responsible for each step of the application of serialized unique identifiers, they consider that the entire process should be entrusted to an economic operator involved in the tobacco trade supervised by the authorities, where the independent third party responsible for generating identifiers should be approved by the EU or MS.

In relation to the method of putting the security feature on the pack/ tin / pouch / item, they prefer Option C (printed security feature).

In relation to the implementation of the independent data storage, they prefer an accreditation or similar system for multiple interoperable storages (organised per manufacturer of territory).

In relation to the development of reporting and query tools, they do not have a clear preference.

In relation to the empowerment of individual consumers to decode and verify a serialized unique identifier with mobile devices, they expressed a positive opinion as such empowerment would increase the control on the supply chain.

Lastly, they expressed additional concerns with regards to the timing for implementation, especially for small manufacturers.

ANNEX 3 – SUMMARY OF STAKEHOLDER COMMENTS

in the context of the **public consultation** on the implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU

CONTENTS

1. Member States and other governmental organisations	2
2. NGOs / Organised civil society.....	5
3. Consumers	8
4. Manufacturers.....	11
5. Operators	15
6. Solution Providers	18
7. Other Organisations.....	21
8. Retailers.....	25

1. Member States and other governmental organisations

Governance

In relation to choice of **governance model**, the majority of government organisations did not favour option A1 (industry led). Instead they had a clear preference for either option for A2 (third party solution) or A3 (mixed model solution). They stressed that the system ultimately chosen should be interoperable across Member States and systems and provide clear enforcement benefit. They also pointed clearly to the need to ensure that the requirements of the FCTC Protocol are respected. Some government organisations expressed fears that a mixed solution may compromise the system and create loopholes, however. One said that the way authorities use the codes should be invisible to industry.

Government Organisations	
A1 Industry operated solution	15.4%
A2 Third party operated solution	34.6%
A3 Mixed-solution	38.5%
No opinion	11.5%

Data storage

In relation to choice of **data storage** location, government organisations' clear priority is the setting in place of a system capable of providing an effective query tool, ensuring data readability and access, and safeguarding the security of stored data – regardless of the option chosen. Some government organisations favoured a distributed system (by Member State) which would nevertheless include a connection to a centralised system, and suggested to look to the system set out under Delegated Regulation 2016/161 for pharmaceutical products, according to which data is stored per MS then shared in a central 'hub'. A few said that there is an increased technical risk with a centralised system, and that each MS should at least have own storage possibilities.

Government Organisations	
B1 Centralised data storage	38.5%
B2 Decentralised data storage	38.5%
No opinion	23.1%

Data carriers

In relation to the **allowed data** carriers, government organisations had a clear preference for allowing for certain flexibility, without providing for a free system – i.e. allowing a limited number of carriers (in particular existing carriers and carriers based on open standards). There were concerns that allowing only one data carrier would create a monopoly and render current equipment void.

Government Organisations	
Option C1: system with a single data carrier	3.8%
Option C2: system with a limited variety of data carriers	61.5%
Option C3: free system allowing any existing data carrier	3.8%
No opinion	30.8%

Delays in reporting

In relation the **allowed delays in reporting**, most government organisations indicated that real time would clearly be the most efficient and effective option, though there was a recognition that it could be technically difficult to implement. Several therefore said that daily is the most feasible option. No government organisation favoured weekly time delays as they say this would undermine the system CHECK.

Government Organisations	
Option D1: real-time (or limited delay)	69.2%
Option D2: once daily reports	23.1%
Option D3: once weekly reports	-
No opinion	7.7%

Security feature

In relation to the choice of **security features**, government organisations were clear that the choice needs to bring meaningful enforcement benefit. They said that consideration must be

given to where they are positioned on packs and some pointed out that it should not obscure or take the place of tax stamps. Several government organisations said that a range of different security features should be allowed and that it should not be possible to counterfeit or reproduce them (a multi-layered system on different parts of the pack is suggested). They said that each Member State should be allowed to choose the most appropriate system and it should be technically feasible for all products and producers and easily authenticated by enforcers. Some pointed to a danger that 'overt' security features could be viewed by consumers as a quality mark.

Government Organisations	
Option S1: affixing	11.5%
Option S2: printing or integrating through a different method	34.6%
Option S3: any method:	46.2%
No opinion	7.7%

2. NGOs / Organised civil society

Governance

In relation to choice of **governance model**, the majority of NGOs indicated that they prefer option A2 (third party solution), with slightly less support for option A1 (industry-led). The main argument was that independence and impartiality could not be guaranteed under option A1, as there is mistrust in relation to the tobacco industry. Option A1 was further said to contradict FCTC provisions 5.3 and 8.12, and to create a monopoly situation that would increase costs, cause market distortion, and create additional burden in the form of increased need for investigation and auditing to monitor industry compliance. Likewise, some respondents pointed out that option A3 was likely to increase overall public-private costs (i.e. for providing compatibility) and may further generate security gaps. Conversely, respondents believed that option A2 ensures a higher degree of impartiality and further enables competition which would lower costs in the long run. However, some respondents stressed that under A2 higher costs related to complex liability issues had to be considered. Respondents opposed to A1 also claimed that there is no evidence to suggest that industry-driven solutions have shown a positive public health effect in the past. For third-party solutions, transparency with regard to the selection procedure was mentioned as the most essential criteria. In general, many respondents missed the scenario "government body & third-party" as a proposed model, which was said to have already shown positive results in some countries.

NGOs	
A1 Industry operated solution	41.1%
A2 Third party operated solution	51.8%
A3 Mixed-solution	3.6%
No opinion	3.6%

Data storage

In relation to choice of **data storage location**, the majority of NGOs indicated option B2 (decentralised storage) as their preferred option. However, more than a quarter indicated no opinion on this point (36%). Whilst option B1 (centralised storage) was said to be easy to implement/administer, likely to reduce the complexity of data assembly and was seen as more cost-effective, this solution was also believed to represent a high risk of being single point in case of failure. Respondents further added that the high volume of data could cause longer response times. A centralised system also required a public tender procedure which could be lengthy and eliminate real market competition in the long run. A decentralised system, on the other hand, was believed to guarantee more flexibility, e.g. allowing Member States to link

data to other national systems/databases. However, interoperability had to be ensured for this option and more attention was required to mitigate risks related to different types of data sets. In the case of geographic decentralisation, respondents further commented that data should be registered firstly in the country of origin or country of first import into the EU, and product data should be registered automatically on the production line in real time and independent of production line owner. In general, any option chosen had to guarantee that data is securely stored, could be easily aggregated and analysed, and was readily accessible by authorities.

NGOs	
B1 Centralised data storage	1.8%
B2 Decentralised data storage	62.5%
No opinion	35.7%

Data carriers

In relation to the **allowed data** carriers, a clear majority of NGOs favoured option C2 (limited variety of allowed data carriers) over all other options. It was seen as the optimal choice as it limited the number of carriers but, at the same time, allowed for some flexibility, especially if operators wanted to use carriers also for other purposes. Multiple carriers also created competition, which could lead to higher quality and lower costs. In general, carriers should be based on common international standards (e.g. GS1), which ensure easy adaptation and potentially enable extension to regions outside the EU. In this respect, some respondents suggested GS1 barcodes for outside packaging and ISS DotCode on unit packs. In any case, carriers should be developed free from tobacco industry involvement. Also, the different requirements of small, medium, and large companies should be taken into account. Lastly, respondents wished for more evidence to support the claim that not all scanners might read certain data carriers and that new scanner development was likely to be required.

NGOs	
Option C1: system with a single data carrier	-
Option C2: system with a limited variety of data carriers	96.4%
Option C3: free system allowing any existing data carrier	1.8%
No opinion	1.8%

Delays in reporting

In relation the **allowed delays in reporting**, the majority of NGOs favoured option D1 (real-time) over option D2 (once daily) and D3 (once weekly). Those in favour of D1 argued that it was the only solution capable of meeting the objectives of the tracking and tracing project. Other options were incapable of sufficiently fighting illicit conduct such as frauds in transit or diversion points, given that time lapses would be unavoidable. Those supporting once weekly reporting pointed out that it was closer to the real-life cycle of the supply-chain process. It was further said that reporting in a timely manner instead of fixed time-intervals could be more appropriate and easier to execute. Respondents also believed that, in line with the FCTC Protocol, governments should require the tobacco industry to bear the all costs and that, for this reason, costs should not be the primary point for consideration. It was also stated that costs were difficult to estimate at this stage but in general were believed to be higher for some groups than others.

NGOs	
Option D1: real-time (or limited delay)	55.4%
Option D2: once daily reports	44.6%
Option D3: once weekly reports	-
No opinion	-

Security feature

In relation to the choice of **security features**, the absolute majority of NGOs indicated option S3 (any method) as their as preferred option. Respondents were largely of the opinion that industry-controlled security features increased the risk of undue legal influence and insights into potential investigations against the industry. In this respect, many respondents believed that Member States should never request necessary/essential data through and/or from the very industry that they control. Furthermore, in accordance with the FCTC Protocol, next to product packs, also identifier systems should be registered and securely identified.

NGOs	
Option S1: affixing	1.8%
Option S2: printing or integrating through a different method	-
Option S3: any method:	92.9%
No opinion	5.4%

3. Consumers

Governance

In relation to choice of **governance model**, a majority of consumers indicated option A2 (third party solution) as their preferred option, with far less preferring options A1 (industry-led) and A3 (mixed solution). The main argument was that independence and impartiality could not be guaranteed under option A1 as there is mistrust in relation to the tobacco industry. Option A1 was further said to contradict FCTC Protocol provisions 5.3 and 8.12, and to create a monopoly situation that would increase costs, cause market distortion, and create additional burden in the form of increased need for investigation and auditing to monitor industry compliance. Conversely, respondents believed that option A2 enabled competition and would therefore lower costs. In addition, as opposed to independent third-party solutions, consumers claimed that there is no evidence to suggest that industry-driven solutions have helped governments to protect public health in the past. For third-party solutions, transparency with regard to the selection procedure was mentioned as the most essential criteria. Lastly, some consumers found the mixed model to be problematic as it may put traceability of products at risk, increase overall public-private costs and potentially generate security gaps.

Consumers	
A1 Industry operated solution	13%
A2 Third party operated solution	78.3%
A3 Mixed-solution	4.3%
No opinion	4.3%

Data storage

In relation to choice of **data storage** location, the majority of consumers preferred option B2 (decentralised storage) and slightly less opted for option B1 (centralised storage). Those opposing centralised storage pointed to risks such as a single point of potential failure, greater need for synchronisation and slower response times, all of which would not be present in a decentralised solution. Geographic decentralisation per Member State with one central focal point was said to allow for decentralised storages to be validated against each other and easier/faster access. Furthermore, respondents commented that this would also allow Member States to integrate data with other local systems (e.g. for taxation or risk analysis purposes). Conversely, those opposing decentralised storages argued that a centralised option best guarantees data integrity and avoids inconsistencies in data sets. It was further argued that centralised data storage would be easier to engineer and implement, reduce complexity of assembling the data and be more cost-effective. Some respondents also pointed out that

combined reliability was always lower in decentralised options than in centralised systems and that additional risk factors existed due to the need for inter-system communication. Irrespective of the option chosen, many respondents found it essential that product data be registered automatically on the production line and independent of production line owners.

Consumers	
B1 Centralised data storage	17.4%
B2 Decentralised data storage	26.1%
No opinion	56.5%

Data carriers

In relation to the **allowed data** carriers, twice as many consumers favoured option C2 (limited variety of allowed data carriers) as option C1 (single data carrier), with no support for option C3 (free system). However, in total about half of all respondents indicated no opinion on this matter. Having more than one carrier was said to offer most flexibility and lead to increased competition, which would most likely improve the functioning of the system and reduce costs. Single carriers, on the other hand, were believed to run the risk of only addressing the needs of larger companies. In general, many respondents said that carriers should ideally be based on open standards and not come from the tobacco industry. It was also mentioned that if current scanners could be programmed to read security features, there would be no need for the introduction of specific scanners. Some respondents suggested the use of a RFID system, which they said allowed for easy scanning of products in large amounts and from a distance. Respondents also pointed to the advantages of data carriers that could be read by smartphone applications, as these would allow consumers verification.

Consumers	
Option C1: system with a single data carrier	17.4%
Option C2: system with a limited variety of data carriers	34.8%
Option C3: free system allowing any existing data carrier	-
No opinion	47.8%

Delays in reporting

In relation to the **allowed delays in reporting**, whilst almost half of all consumers indicated they did not have an opinion on any of the options, there was a clear preference for option D1 (real-time) over options D2 (once daily) and D3 (once weekly) (9%). The real time option was said to be the only option that would meet the overall objectives of the tracking and tracing project. Other options jeopardise the ability to fight illegal tactics such as frauds in transit, carousel frauds, and diversion points. Many respondents also mentioned that there are no differences between the different options with respect to the total volume of transmitted data. Therefore, costs should be very similar.

Consumers	
Option D1: real-time (or limited delay)	34.8%
Option D2: once daily reports	13.0%
Option D3: once weekly reports	8.7%
No opinion	43.5%

Security feature

In relation to the choice of **security** features, whilst about half of all consumers indicated no opinion on any of the options, there was a slight preference for option S3 (any method) over option S2 (printing or integrating) and option S1 (affixing). In general, the majority of consumers were of the opinion that any form for security feature had to be developed fully independently of the tobacco industry and should be subject to strict and transparent scrutiny measures. Furthermore, it was said to be important that identifier systems were registered and that it be possible to identify them clearly and securely.

Consumers	
Option S1: affixing	8.7%
Option S2: printing or integrating through a different method	17.4%
Option S3: any method:	21.7%
No opinion	52.2%

4. Manufacturers

Governance

In relation to choice of **governance model**, manufacturers had a clear preference for option A1 (industry-led solution). According to many, option A2 (3rd party-led solution) would mean substantially increased costs for the industry compared to option A1 (up to 3 times the cost of option A1 according to one manufacturer, although the majority said it is not possible to provide exact estimates at the current stage). Bigger manufacturers said that the substantial investments in infrastructures they have already made would be rendered void under a third party solution. Manufacturers also expressed concern regarding how issues of liability and accountability would be dealt with under a third party system. Regarding option A3 (mixed solution), comments were more limited but some expressed concern that it would compromise responsibility for accuracy of data and lead to a lack of accountability. SMEs, in particular those producing niche products and tobacco products other than cigarettes, argued that they are likely to incur high costs regardless of governance model (estimates vary from 9e million to 140e million extra in costs per year, and increased unit pack costs of 0,05e to 0,20e).

Manufacturers	
A1 Industry operated solution	75.0%
A2 Third party operated solution	-
A3 Mixed-solution	15%
No opinion	10%

Data storage

In relation to choice of **data storage** location, a slightly higher number of manufacturers expressed a preference for a decentralised system divided according to manufacturer (where each manufacturer is responsible for selection of an independent third party), which they said is the most technically feasible option and in keeping with Article 15 of the TPD. These manufacturers pointed to what they say are the higher risks associated with a centralised system, such as business interruptions in the case of connectivity breakdown, security issues, slower speed due to high volume of data (they cite approximately 230 manufacturers with 24-30 billion packs per year and at least 3 changes of ownership per product en route) and the risk of lengthy tendering procedures. Nevertheless, several manufacturers also stressed the importance of only requiring submission of data to one location. Most manufacturers are not in favour of geographical decentralisation which they say will not facilitate a global overview of products and will result in higher costs for manufacturers. It should be noted, however, that several smaller manufacturers favoured a centralised system which they said would simplify the data reporting process and be less burdensome.

Manufacturers	
B1 Centralised data storage	35%
B2 Decentralised data storage	60%
No opinion	5%

Data carriers

In relation to the **allowed data** carriers, there was a strong preference amongst manufacturers for allowing a limited number. It is claimed that a system with a single data carrier would be too restrictive as well as detrimental for SMEs, while a fully open system would result in problems for operators and scanners. For the limited number of allowed data carriers, manufacturers were in general in favour of allowing open standards, especially existing and future GS1 standard barcode for outside/aggregated packaging and ISS DotCode for unit packs, and several point out that standard supply chain scanners are often already built to read GS1 codes.

Manufacturers	
Option C1: system with a single data carrier	5%
Option C2: system with a limited variety of data carriers	90%
Option C3: free system allowing any existing data carrier	-
No opinion	5%

Delays in reporting

In relation the **allowed delays in reporting**, the majority of manufacturers have a preference for a once-daily delay. They are of the opinion that introducing real-time reporting would require significant upgrades to IT infrastructures and lead to increased complexity for distributors and SMEs (one estimation of an extra 0,60e per pack). They claim that allowing the possibility to upload reports in batches is necessary in order to save manpower and that the concept of 'real time' requires further definition. Manufacturers on the whole believe that the requirement should be for information to be reported in 'in a timely manner', and not less than at 1-day intervals. There is a general recognition that once weekly reporting would be less than effective.

Manufacturers	
Option D1: real-time (or limited delay)	5%
Option D2: once daily reports	70%
Option D3: once weekly reports	20%
No opinion	5%

Security feature

In relation to the choice of **security features**, manufacturers favour a multi-layered approach. Some suggest using the unique identifier as the visible dimension of the security feature. Several SMEs said that flexibility and choice are important factors for them, and consideration should be given to the different types of packaging materials (whether paper, wood, plastic etc.) as some solutions (such as forensics) are not suitable for all.

Manufacturers	
Option S1: affixing	5%
Option S2: printing or integrating through a different method	5%
Option S3: any method:	80%
No opinion	10%

General comments – Manufacturers: Manufacturers emphasised that any additional step in the manufacturing process will from their perspective lead to delays. Should the role of a third party be limited to code generation, however, one manufacturer believed it would be technically feasible.

Several manufacturers stress that the most crucial information that the system will provide relates to changes of ownership along the supply chain, as this is essential for identifying those who make products available to smugglers, and that more emphasis should be placed on this aspect than on unique identifier generation. They also stress that interoperability between systems will be essential.

Manufacturers say a big concern are products imported from outside the EU, and point to the case of transport facilities, warehouses and sales that happen after the goods have left the third-country manufacture but before they reach the EU. For export from EU to third countries, they say the shipment/sale to the first non-EU country should be the last required entry.

It was also pointed out that in certain cases, goods need to be returned by retailers to the last economic operators, and that recording of such movements needs to be provided for in the system. The possibility to aggregate (e.g. in one pallet/master case) various different products types and products from various manufacturers should be foreseen.

SMEs/manufactures of niche tobacco products stress that illicit trade in their sector is negligible.

5. Operators

Governance

In relation to choice of **governance model**, operators clearly favour option A1 (industry led). They nonetheless said that further clarification regarding what "governance" will mean is necessary, e.g. whether it will entail only generation of unique identifiers, or responsibility for the functioning of whole system. Still, it was highlighted that option A1 is likely to be easiest to implement, as only one entity would be responsible for the whole process, which would also be beneficial from the point of view of the competent authorities. Option A1 was also preferred for economic reasons, given the investments already made by the industry and infrastructures in place, which operators say are capable of meeting TPD requirements. A third party solution is criticised as third parties should not control the supply chain and there is no requirement in the TPD to involve them. In addition it would require additional costs and investments, with some limited evaluations provided.

Operators	
A1 Industry operated solution	89.7%
A2 Third party operated solution	1.1%
A3 Mixed-solution	8%
No opinion	1.1%

Data storage

In relation to choice of **data storage location**, operators had a clear preference for decentralised storage as per manufacturer. This option was considered less complex to set up and operate. In addition it they said that this reflects the systems already in place and changing would require a modification of all routing systems. Operators nonetheless recognised that the decentralised model could entail some difficulties in the management of the recorded information, which should be sent to different destinations, but added that this complexity could be offset by the creation of a HUB dispatcher. The main concerns expressed in relation to a centralised option include a single potential pint of failure, lengthy response times due to data volume and higher costs and complexity. However it was acknowledged that the centralised model has some advantages, as a single destination repository simplifies the data handling.

Operators	
B1 Centralised data storage	10.3%
B2 Decentralised data storage	86.2%
No opinion	3.4%

Data carriers

In relation to the **allowed data carriers**, a clear majority of operators indicated option C2 (limited variety of data carrier) as their preferred option. The vast majority is in favour of using international open standards, i.e. GS1, and say that using ISS DotCode on unit packs would enable large amounts of information to be stored in a small area and printed at high speed. They also pointed to EPCIS interface. The use of such standards would allow interoperability and enable operators to use the infrastructures already in place. On the other hand operators did not consider option C1 (single data carrier) to be sufficiently flexible, and said that option C3 (free system) would carry the risk that not all scanners will be able to read all codes.

Operators	
Option C1: system with a single data carrier	2.3%
Option C2: system with a limited variety of data carriers	94.3%
Option C3: free system allowing any existing data carrier	1.1%
No opinion	2.3%

Delays in reporting

In relation the **allowed delays in reporting**, operators are clearly in favour of option D2 (once daily reports). It should be pointed out that operators said that the concept of 'real-time' should be further defined. It emerged that the main reason for discarding option D1 (real-time) is economic, as it would require additional costs which operators say are prohibitive, especially for SMEs, and would also affect their daily operations. Usually products are scanned throughout the order preparation, but the shipment takes place after. In addition certain operators would not be able to transmit in real-time (e.g. in warehouses or areas with

limited coverage for mobile devices). Some said there was a lack of tangible benefit to justify the necessary expenses that a real-time delay would require.

Operators	
Option D1: real-time (or limited delay)	6.9%
Option D2: once daily reports	80.5%
Option D3: once weekly reports	9.2%
No opinion	3.4%

Security feature

In relation to the choice of **security features**, operators are clearly in favour of option S3 (any method). Comments on this option were limited as the main focus of operators remained on the supply-chain.

Operators	
Option S1: affixing	2.3%
Option S2: printing or integrating through a different method	4.6%
Option S3: any method:	85.1%
No opinion	8%

6. Solution Providers

Governance model

In relation to choice of **governance model**, solution providers expressed a preference for involvement of a third party with option A3 (mixed model) being a favoured option. Even solution providers opting for A1 (industry-led) recognised that this option would require additional state controls. Most solution providers had difficulty in estimating costs. They either expected options A1 and A2 to have a similar cost or A1 to be cheaper. A2 is argued to be more expensive due to duplication of procedures at the production sites. Regarding potential allocation of responsibilities, there are suggestions that serialisation/generation of UID should be under control of the authorities, while the operation of hardware by the industry may pose lesser risks for the system's integrity. It is also pointed out that the sector is not homogenous, i.e. the needs of operators differ, and therefore sufficient flexibility in organising inner processes should be provided.

Solution Providers	
A1 Industry operated solution	21.4%
A2 Third party operated solution	14.3%
A3 Mixed-solution	50%
No opinion	14.3%

Data storage location

In relation to choice of **data storage location**, solution providers recognised the existing trade-offs between various options for organising data storage. Even if solution providers seemed to prefer decentralised options, they generally see a need for certain centralisation, e.g. one point from which all information on a given product can be retrieved. Some of the proponents of a decentralised system also acknowledge a need for centralised services such as data broker services, which are necessary to assist distributors and wholesalers in transmitting the data to the right storage. Concerns as to the full centralisation, i.e. the establishment of a single EU-wide storage, are mainly based on the risks of creating a single point of technical failure as well as potential inefficiencies related to the volume of processed data. The data storage model should protect the confidentiality of commercial data (among others by proper segregation of the data). Individual solution providers point to such new developments relevant in the context of data storage model as cloud storage or a shift to digital tax settlement.

Solution Providers	
B1 Centralised data storage	32.1%
B2 Decentralised data storage	46.4%
No opinion	21.4%

Data carriers

In relation to choice of **allowed data carriers**, solution providers clearly preferred a limited variety of data carriers. Several solution providers referred to open standards and called for applying the data carriers standardised by GS1. As a rationale for permitting the limited variety of data carriers, solution providers drew attention to differences in the physical settings of production and logistic processes (e.g. reading distances, size of packaging or data carriers' positioning) and important costs for certain logistic operators related to a potential switch to 2D barcodes.

Solution Providers	
Option C1: system with a single data carrier	14.3%
Option C2: system with a limited variety of data carriers	67.9%
Option C3: free system allowing any existing data carrier	3.6%
No opinion	14.3%

Delays in reporting events

In relation to choice of **allowed time delays**, solution providers were generally in favour of real-time reporting. Even those solution providers who preferred once daily reports often acknowledge the importance of real-time reporting for the control functions to be performed by the authorities. One solution provider questioned the viability of longer time delays by arguing that "breaking the chain by delays in data updating undermines the idea of tracing". It is also commented that a higher frequency of reporting does not increase costs, and may actually provide for some savings on the local storage. However, a distinction is made between data acquisition and data transmission, the former requires interoperability with company's other systems and hence may be costly to be performed in real time.

Solution Providers	
Option D1: real-time (or limited delay)	53.6%
Option D2: once daily reports	28.6%
Option D3: once weekly reports	-
No opinion	17.9%

Security feature

In relation to choice of **security features**, many responses of solution providers reflected the nature/type of solutions offered by individual providers. For most solution providers, providing consumers with visible security features and the possibility to decode unique identifiers with mobile devices is important. Several responses received from solution providers gave examples of actual and potential security features.

Solution Providers	
Option S1: affixing	32.1%
Option S2: printing or integrating through a different method	25%
Option S3: any method:	39.3%
No opinion	3.6%

7. Other Organisations

Diverse organisations identified themselves under the '**other organisation**' category. A significant number were trade associations representing tobacco manufacturers – in particular manufacturers of tobacco products other than cigarettes and roll your own, including SMEs. Operator/wholesaler organisations were also represented as were a smaller number of public health organisations/NGOs. Certain employers' confederations and chambers of commerce also replied under this category.

Governance model

In relation to choice of **governance model**, trade associations representing tobacco manufacturers showed a clear preference for option A1 (industry-led) while pointing to what they say would be the increased costs of implementing option A2 (third party solution) and liability and accountability issues relating to option A3 (mixed solution). Several of these associations said that costs will be higher for smaller companies and that solution needs to reflect the realities of this SME sector, taking both initial investments and ongoing operating costs into account. Some also stressed that there should be some flexibility regarding requirements as certain niche products, such as nasal snuff, will have specific pack constraints. Wholesaler/operator organisations stressed that the choice of governance model should not affect operational feasibility and affordability and usually had a preference for option A1. In contrast to the above, public health organisations/NGOs stressed that option A1 cannot be considered to be compatible with FCTC Protocol requirements and should be discounted.

Other Organisations	
A1 Industry operated solution	76%
A2 Third party operated solution	10.6%
A3 Mixed-solution	7.7%
No opinion	5.8%

Data storage location

In relation to choice of **data storage location**, trade associations which represent smaller manufacturers showed a preference for centralised storage, which they say would simplify the data reporting process and be less burdensome. Associations representing larger manufacturers preferred a decentralised option, divided according to manufacturer. Wholesalers/operator organisations stress the importance of ensuring that data is only reported to a single location. Public health organisations/NGOs said that the priority is to ensure that

the data is easily accessed, secure and readable so as to guarantee the effectiveness of the system. They say the location is not of central concern for them.

Other Organisations	
B1 Centralised data storage	17.3%
B2 Decentralised data storage	70.2%
No opinion	12.5%

Data carriers

In relation to choice of **allowed data carriers**, there was a general agreement that clearly defined standards and interoperability are crucial. Trade associations representing tobacco manufacturers stressed that open standards should be favoured. An employers' confederation echoed this and said that it is important that all products can be handled with the same equipment. Wholesaler/operator organisations said that data carriers must be practical for printing. One wholesaler organisation said that the task of coordinating ISO compliant media, including aggregations, should be left to the tobacco industry and the wholesalers alone.

Other Organisations	
Option C1: system with a single data carrier	1%
Option C2: system with a limited variety of data carriers	92.3%
Option C3: free system allowing any existing data carrier	1%
No opinion	5.8%

Delays in reporting events

In relation to choice of **allowed time delays**, there was a general preference for once daily reporting. Trade associations representing tobacco manufacturers said that real-time reporting would bring increased burden, especially for SMEs, and that certain docking systems only synchronise recorded information at intervals. Wholesaler/operator organisations said that real-time reporting would lead to increased risk that the supply chain could be blocked due to system failure and said that its benefits are not clear. One lobbyist for the tobacco manufacturing sector indicated that real time would be feasible. Public health organisations/NGOs pointed out that tobacco manufacturers will be the ones to bear overall

costs, but bureaucratic impact on small operators should be kept to a minimum where possible.

Other Organisations	
Option D1: real-time (or limited delay)	10.6%
Option D2: once daily reports	78.8%
Option D3: once weekly reports	6.7%
No opinion	3.8%

Security feature

In relation to choice of **security features**, trade associations representing manufacturers of other tobacco products stressed that flexibility is needed as not all solutions are suitable for different packaging types, and certain niche products, such as nasal snuff, will have specific pack constraints. Some said that the unique identifier should be used as the security feature. It was highlighted that the security feature should be capable of authenticating the entire product and not just the feature itself. Others stressed that Member States should be allowed to choose alternative solutions. Carton manufacturers stressed the importance for consumers of being able to authenticate the products at the time of purchase.

Other Organisations	
Option S1: affixing	1.9%
Option S2: printing or integrating through a different method	7.7%
Option S3: any method:	82.7%
No opinion	7.7%

In their **general comments**, other organisations added that the future system should foresee an easy 'check-out' for products being exported outside of the EU. It should also foresee the recording of returns to the last operator (that may be made by the retailer) as well as the possibility to aggregate different product types within one pallet/master case.

Wholesaler/operator organisations said that the readiness of the operating sector needs to be closely assessed and that it can vary in each Member State, with some operators only being active in a single Member State. Some organisations claim that initial industry investments will not cover the ongoing operational costs for this sector and that the system should be developed on the basis of ongoing cost sharing with the industry. One said the sector should only be obliged to report receipt of products only. A manufacturer operating on an island off the mainland said that it would not have capacity to comply with traceability requirements beyond the sale to the first customer. It was also highlighted that the situation of small distributors and agents in the supply chain should be taken into account.

8. Retailers

Governance model

In relation to choice of **governance model**, retailers clearly preferred option A1 (industry-operated solution) over option A3 (mixed solution), with no support for option A2 (third party solution). The main reason was that industry is said to have the most experience. Most respondents also did not believe that an industry-operated solution would require additional control measures on the side of public authorities. Further, retailers did not agree that supply chain monitoring by an independent third-party was necessary as it would add unnecessary complexity to the system, requiring interference into the private premises of manufacturers. In general, it was pointed out that particularly small retailers had no financial means and/or expertise to support industry driven solutions and that all solutions would mean additional efforts for retailers. Irrespective of the model chosen, it had to be guaranteed that the responsibility for accountability throughout the process is placed on the manufacturer.

Retailers	
A1 Industry operated solution	85.7%
A2 Third party operated solution	-
A3 Mixed-solution	14.3%
No opinion	-

Data storage location

In relation to choice of **data storage location**, the large majority of retailers indicated their preference for option B2 (decentralised storage) while a smaller number preferred option B1 (centralised storage). It was said that experience had shown that centralised data storages were not ideal for retailers. Also, they ran the risk of long(er) response times and any possible downtime would have a higher overall impact. Decentralised storages, audited by independent parties, on the other hand, were said to be easier adaptable to individual manufacturers and reduced technical complexities related to data availability. Ideally, these storages should be split up per manufacturer. In the same vein, many respondents preferred a solution in which, despite decentralisation, data only needed to be submitted via one focal point in the system.

Retailers	
B1 Centralised data storage	17.9%
B2 Decentralised data storage	78.6%
No opinion	3.6%

Data carriers

In relation to choice of **allowed data carriers**, retailers showed a clear preference for option C2 (limited variety of allowed data carriers). Whilst having only one type of data carrier would make manipulation and/or falsification of the carrier easier, multiple carriers were believed to allow for higher security and more flexibility with respect to the traceability of tobacco products. The majority of retailers commented on the importance of maintaining existing standards. GS1 compliant carriers should be used on outside packaging and ISS DotCode on unit packs. It was further recommended that existing carriers should be used and, if necessary, reconfigured. Likewise, respondents pointed to the importance that one scanner should be able to read all carriers used.

Retailers	
Option C1: system with a single data carrier	7.1%
Option C2: system with a limited variety of data carriers	89.3%
Option C3: free system allowing any existing data carrier	-
No opinion	3.6%

Delays in reporting events

In relation to choice of **allowed time delays**, most retailers indicated preference for option D2 (once daily) over option D1 (real-time) and option D3 (once weekly). Real-time reporting was said to be difficult to realise in practice and would come with additional costs, whilst once daily reports matched the real-life product cycle more accurately. In this respect, it was also suggested to have clear and timely requirements setting out until when reporting had to take place instead of setting fixed-time intervals, which were difficult to realise in practice due to differences in supply chains. Lastly, respondents found it difficult to estimate possible increases in costs at this point in time.

Retailers	
Option D1: real-time (or limited delay)	7.1%
Option D2: once daily reports	82.1%
Option D3: once weekly reports	3.6%
No opinion	7.1%

Security feature

In relation to choice of **security features**, the majority of retailers indicated their preference for option S3 (any method) over the other two options (affixing; printing) as this question related less directly to retailers' concerns. In general, respondents mentioned that for printing and integrating security features, the costs for smaller producers (e.g. cigar producers) could be disproportionately high. Therefore, it was important to ensure that they could be easily affixed to the pack/box.

Retailers	
Option S1: affixing	3.6%
Option S2: printing or integrating through a different method	3.6%
Option S3: any method:	85.7%
No opinion	7.1%

ANNEX 4 – RELATIONSHIP BETWEEN ISSUES, OBJECTIVES AND POLICY OPTIONS

Main issues to address	Why is this an issue?	Operational objectives	Policy options
1a) Marking packages with a unique identifier	In order to combat fraud of legally produced tobacco products, the TPD requires all unit packets of tobacco products to be marked with a unique identifier. This is the cornerstone of the traceability system. In order to meet the requirements relating to system independence, overall control of this process must be with the authorities.	To ensure the marking of packs with a unique identifier whilst guaranteeing independence of the traceability system by appropriate assignment of roles and tasks to relevant parties	a) Industry operated b) Third party operated c) Mixed solution
1b) Recording and transmitting data	To provide authorities with information that is of added value for their enforcement activities, economic operators should transmit information in a timely manner. Maximum permitted time lags should be set.	To ensure effective surveillance and monitoring throughout the supply chain by determining the most suitable permitted time lag between an event occurrence and its recording and transmission to the data storage facility	a) Near real time b) One day time lag c) One week time lag
1c) Processing, storing and accessing data	To facilitate the enforcement activities of authorities, the stored product information should be readily accessible by them and provide as comprehensive an overview of the supply chain as possible.	To ensure effective surveillance and monitoring throughout the supply chain by identifying a system architecture which guarantees full and timely access by competent authorities and the Commission to the data recorded	a) Decentralised per manufacturer/importer b) Decentralised per MS c) Combined model
2) Compatibility of components of the traceability system	The process of recording and transmitting data should be facilitated for economic operators (who will need to	To ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers	a) Single data carrier per level b) Limited variety of data carriers per level

	ensure compatibility with external components such as scanners) by ensuring that information is encoded on packs in a pre-defined way. The authorised variety of data carriers should be set		d) Free system
3) Security features	Selecting an appropriate application method for security feature is important for ensuring they fulfil their authentication function, comply with Article 16 TPD, take into account different manufacturing processes and packaging types and allow room for future innovation.	To facilitate the authentication of tobacco products by an optimal selection of application methods for security features	a) Printing or affixing b) Printing or affixing or a combination of printing and affixing

ANNEX 5 – DETAILED EVALUATION OF EACH POLICY OPTION

Part of the Everis Report¹

7.1. Governance model

7.1.1. 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, the first Protocol to the Convention, was adopted on 12 November 2012. The Protocol requires 40 Parties to enter into force (WHO - FCTC, 2017). As of January 2017 (United Nations, 2017), 24 Parties² plus the European Union have ratified, accepted or approved the FCTC Protocol. Therefore, the FCTC Protocol has not entered into force yet.

On March 2014, the Council of the EU adopted the revised Tobacco Products Directive. Taking a coherent position, the EU formally confirmed the FCTC Protocol (24/06/2016). By ratifying the Protocol³, the EU indicates its consent to be bound to the instruments of the Protocol⁴ that fall into the categories and areas of Union competence.

According to the declaration submitted by the European Union pursuant to article 44 of the FCTC Protocol, the EU has exclusive competence to act with respect to the matters covered by the FCTC Protocol that fall under the scope of the common commercial policy of the EU (Article 207 TFEU). In addition, the EU has exclusive competence to act with regard to matters covered by the FCTC protocol that fall under the scope of customs cooperation (Article 33 TFEU), approximation of laws in the internal market (Articles 113 and 114 TFEU), judicial cooperation in criminal matters (Article 82 TFEU) and definition of criminal offences (Article 83 TFEU), only insofar as the provisions of a Union act establish common rules that may be affected or altered in scope by provisions of the FCTC protocol.

We consider the FCTC applicable in the territory of the EU for those matters that fall under the scope of the competences of the Union.

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

¹ A detailed bibliography for Annexes 5 and 6 is set out at the end of Annex 6.

² Austria, Burkina Faso, Comoros, Congo, Cote d'Ivoire, Ecuador, France, Gabon, Gambia, Iraq, Latvia, Lithuania, Mali, Mongolia, Nicaragua, Panama, Portugal, Saudi Arabia, Senegal, Spain, Sri Lanka, Swaziland, Turkmenistan, Uruguay.

³ "Act of formal confirmation" is used as an equivalent for the term "ratification" when an international organization expresses its consent to be bound to a treaty." [Arts.2 (1) (b bis) and 14, Vienna Convention on the Law of Treaties between States and International Organizations or between International Organizations 1986].

⁴ "Ratification defines the international act whereby a state indicates its consent to be bound to a treaty if the parties intended to show their consent by such an act." [Arts.2 (1) (b), 14 (1) and 16, Vienna Convention on the Law of Treaties 1969].

The legal compliance of the three alternatives proposed for a Governance model with the requirements of the FCTC Protocol and the TPD is analysed in this chapter. In particular, attention is put in articles 8.1, 8.2, 8.3, 8.12 and 8.13 of the FCTC Protocol and art. 15.1 of the TPD, which are the most critical regarding the Governance model and the allocation of tasks.

Art.	Analysis	Compliance		
		A1	A2	A3
8.2. FCTC C Prot	<p>Content</p> <p>Each Party shall establish, in accordance with this Article, a tracking and tracing system, <u>controlled by the Party</u> 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.</p>	Yes	Yes	Yes
	<p>Impact on the Governance model</p> <p>According to this article, the tracking and tracing system shall be controlled by the Parties to ensure that the system allows to meet the general objectives and goals of the TPD and the FCTC Protocol. This does not forbid that the industry operates some aspects the system (nor the TPD, nor the FCTC Protocol state that the industry cannot generate the codes or mark the unit packets of tobacco products, for example), as far as the overall system remains under the control of the Party.</p>			
	<p><u>How does this requirement of control impact the Governance model?</u></p> <p>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 (<i>conditio sine qua non</i>) 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).</p>			
	<p>Corrective measures</p> <p>The following measures are foreseen in each of the alternatives to ensure the control of the system by the public authorities:</p> <p>(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</p>			

Art.	Analysis	Compliance		
		A1	A2	A3
	<p>the full time physical presence of enforcement officers on the manufacturers' (and importers') facilities⁵ 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.</p> <p>(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. Public authorities may be required to approve the independent third parties, only after verifying their independence and technical capabilities.</p> <p>(Alternative A3) The control in this alternative is executed through:</p> <ul style="list-style-type: none"> • 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. FCT C Prot	<p>Content</p> <p>With a view to enabling effective tracking and tracing, <u>each Party shall require</u> that unique, secure and non-removable identification markings (hereafter called unique identification markings), such as codes or stamps, <u>are affixed to or form part of all unit packets</u> 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.</p>	Yes	Yes	Yes
	<p>Impact on the Governance model</p> <p>The obligation in this article concern the Parties, who shall <u>require</u> 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. With the adoption of the TPD by the</p>			

⁵ 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
	<p>Council of the EU, the EU and the Member States are meeting the requirement of art. 8.3 of the FCTC Protocol.</p> <p>Corrective measures N/A</p>			
8.12. FCT C Prot	<p>Content</p> <p><u>Obligations assigned to a Party shall not be performed by or delegated to the tobacco industry.</u></p> <p>Impact on the Governance model</p> <p>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:</p> <ul style="list-style-type: none"> - 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 (art. 8.3 FCTC Protocol). <p>This paragraph of the FCTC Protocol does not imply that the operations of the tracking and trace system shall not be delegated to the industry. The scope of this paragraph implies that the obligations assigned to a Party cannot be delegated. In the EU, a tracking and tracing system is being established by means of art. 15 TPD and envisaged implementing and delegated acts. Following Art 8(12) of the FCTC Protocol, the EU cannot delegate its legislative tasks to the industry for self-regulation.</p> <p>The FCTC Protocol does not state that these obligations cannot be delegated at all. It states that they cannot be delegated to the tobacco industry only. This gives room to a delegation to a third party independent to the industry.</p> <p>It is reasonable to maintain that the descriptions of the Governance models comply with the Article 8(12) FCTC Protocol. In none of the three alternatives proposed for a Governance model obligations assigned to the Parties are performed or delegated to the tobacco industry.</p>	Yes	Yes	Yes

Art.	Analysis	Compliance		
		A1	A2	A3
	<p>Corrective measures</p> <p>N/A</p>			
8.13. FCT C Prot	<p>Content</p> <p>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.</p>	Yes	Yes	Yes
	<p>Impact on the Governance model</p> <p>The contacts between the industry and the public 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.</p>			
	<p>Corrective measures</p> <p>N/A</p>			
15.1 TPD	<p>Content</p> <p><u>Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier.</u> 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.</p>	Yes	Yes	Yes
	<p>Impact on the Governance model</p> <p>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 of this article, there are different scenarios which ensure that all tobacco products are marked as required:</p> <ul style="list-style-type: none"> ○ Member States mark themselves all the unit packets (unrealistic scenario). ○ Member States appoint/pre-approve independent third 			

Art.	Analysis	Compliance		
		A1	A2	A3
	<p>parties to mark all the unit packets (scenario of alternative A2).</p> <ul style="list-style-type: none"> 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). This implementation is not against art. 8.12 of the FCTC Prot., as described in the analysis performed above. 			
	<p>Corrective measures</p> <p>The measures to ensure control in the context of art. 8.2 FCTC Protocol also apply.</p>			

7.1.2. 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						
After the legal review performed, the team agrees with the compliance of the alternatives for a Governance model with the legal requirements of the TPD (art. 15) and the FCTC Protocol (art. 8).							
1	Technical feasibility	8,33%	100%				
				100	69	94	

(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
1-1	Ability to ensure that the unique identifier is applied (printed/affixed) on time and without major impacts on the production lines	2,08%	25%				Sources: <ul style="list-style-type: none"> •(Directive 2014/40/EU of the European Parliament and of the Council, 2014) •(European Commission - Feasibility 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: <ul style="list-style-type: none"> •(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							

(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
		<p>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.</p> <p>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.</p>					
1-3	Ability to adapt to all tobacco products	2,08%	25%				Sources: <ul style="list-style-type: none"> •(Directive 2014/40/EU of the European Parliament and of the Council, 2014) •(European Commission - Targeted stakeholder consultation TPD, 2015) •(Ross, 2015)
		<p>Description:</p> <p>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 2014. 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.</p> <p>In the case of option A2, where the marking of the tobacco products is allocated to 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</p>					

(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
		product manufactured or imported. A list of companies offering these services may also be found in (Ross, 2015, p. 9).					
1-4	Ability to apply the UID on all aggregation packaging levels	2,08%	25%				Sources: <ul style="list-style-type: none"> •(Directive 2014/40/EU of the European Parliament and of the Council, 2014) •(Ross, 2015)
		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 master case 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.					
2	Interoperability	8,33%	100%	 50	 100	 75	
2-1	Ensure that the tracking and tracing system is interoperable with any other	8,33%	100%				Sources: <ul style="list-style-type: none"> •(Ross, 2015) •(European Commission - Feasibility Study, 2015) •(KPMG and GS1, 2014)

(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
	supply chain equipment	<p>Description:</p> <p>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).</p> <p>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. In 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.</p>					
3	Ease of operation	8,33%	100%	 100	 50	 100	
3-1	Impact on the operational processes of the manufacturers	8,33%	100%				<p>Sources:</p> <ul style="list-style-type: none"> •(European Commission - Feasibility Study, 2015) <p>Description:</p> <p>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 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</p>

(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
		the manufacturers to install, operate and maintain their equipment.					
4	System integrity	12,50 %	100%	 50	 92	 83	
4-1	Ensure the integrity of the system when multiple parties are involved	4,17%	33,33 %				Sources: •(European Commission - Feasibility Study, 2015)
		Description: The integrity of the system is not challenged when all the system is managed by a single actor, as it 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 national authorities and/or third parties required for this solution need 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.					
4-2	Ensure that the independence of the system from the industry is maintained in the medium/long term	4,17%	33,33 %				Sources: •(European Commission - Feasibility Study, 2015)
		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 run is ensured by: <ul style="list-style-type: none"> • An initial assessment by the Commission 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					

(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
		<p>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.</p> <p>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 competent authorities.</p>					
4-3	Provide additional levels of independence and transparency to the tracking and tracing system	4,17%	33,33 %				<p>Sources:</p> <ul style="list-style-type: none"> •(European Commission - Feasibility Study, 2015) •(Ross, 2015)
		<p>Description:</p> <p>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, <i>per se</i>, does not provide additional levels of independency and transparency to the tracking and tracing system.</p> <p>In option A2, the system is operated entirely by an independent third party, whose independency and capabilities are assessed by the Commission. 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.</p> <p>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.</p>					
5	System security	12,50 %	100%				
5-1	Guarantee of a secure	12,50 %	100%				<p>Sources:</p> <ul style="list-style-type: none"> •(European Commission -

(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
	environment for the generation of unique identifiers						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: <ul style="list-style-type: none"> • 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 trade	25,00 %	100%				Sources: •(European Commission - Targeted stakeholder consultation TPD, 2015) •(European Commission - Public 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.					

(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
		<p>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.</p> <p>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”.</p>					
7	Administrative / financial burden for economic stakeholders	12,50 %	100%	 100	 50	 75	
7-1	Burden for economic stakeholders	12,50 %	100%				<p>Sources:</p> <ul style="list-style-type: none"> •Cost Analysis •(European Commission - Feasibility Study, 2015) •(European Commission - Impact Assessment FMD, 2008) <p>Description:</p> <p>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.</p> <p>Option A2, on the contrary, imply 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.</p> <p>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</p>

(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
		<p>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).</p> <p>More details may be found in the cost analysis for the governance model.</p>					
8	Administrative / financial burden for public authorities	12,50 %	100%				
				0	100	100	
8-1	Burden for public authorities	12,50 %	100%				<p>Sources:</p> <ul style="list-style-type: none"> •Cost Analysis •(Eurostat, 2013) •(European Commission - Feasibility Study, 2015)
		<p>Description:</p> <p>When analysing the burden for public 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 does not forbid the industry to be in charge of generating the UID and printing and affixing them into all units of tobacco products. However, the TPD requires that the Member States ensure that all unit packets of tobacco products are marked. 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.</p> <p>For options A2 and A3, the financial burden for the public authorities presents minor differences.</p> <p>More details may be found in the cost analysis for the governance model.</p>					

Table 1: Governance model – detailed evaluation of the policy options

7.2. 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	
<p>B1 is considered not to be compliant with the primary requirements because the A-8 criterion of this category is not fully accomplished.</p>								
A-1	<p>Ability to store the entry, intermediate movements and the final exit of the unit packets of tobacco products</p>	0,00%	12,5%					<p>Sources:</p> <ul style="list-style-type: none"> •(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 Commission - Targeted stakeholder consultation TPD, 2015)
				<p>Description:</p> <p>The optimal solution shall be based on open standards, to the maximum extent possible, if available and applicable.</p> <p>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.</p> <p>In this regard, the GS1 System Architecture is a collection of standards</p>				

(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
								<p>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.</p> <p>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.</p> <p>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.</p> <p>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 <u>services</u> (formerly named GS1 EPCIS) on the basis of its completeness, flexibility and proved functioning in international supply chain production systems. Also, some stakeholders consultations within the pharma and tobacco supply chain showed wide support of this standard.</p> <p>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.</p>
A-2	Ability to store information about	0,00%	12,5%					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
	any transaction of tobacco products	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.						
A-3	Guarantee that an external auditor shall be able to monitor the activities of the Data Storage Service Provider	0,00%	12,5%					Sources: •(O'Reilly, 2016) •(Amazon, 2017) •(Google, s.f.) •(Microsoft, 2017)
		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. 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	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						

(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
	shall have full access to the data storage solution	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”,						

(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
								<p>using the plural to refer to the data storage providers. On the other hand, Article 15(8), 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.</p> <p>Therefore, having said the above, B1 fails in the scoring of this criterion.</p> <p>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.</p>
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%					<p>Sources:</p> <ul style="list-style-type: none"> •(Tanenbaum & Steen, 2006) •(European Commission - Targeted stakeholder consultation TPD, 2015) •(O'Reilly, 2016) •(Tate & al., 2016) • •(Kang, Park, & Youm, 2016) •(Amazon web services, 2016)
				<p>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</p>				

(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
								<p>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.</p> <p>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.</p> <p>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 read accesses.</p> <p>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</p>

(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
		according to current state of play: “hot” tier with short response times and “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
<p>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.</p> <p>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.</p> <p>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</p>								

(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
								<p>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.</p> <p>Therefore, option B1 achieves the highest scoring because is the most effective (i.e. less complexity and better performance when writing).</p> <p>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.</p> <p>Options B2 and B4 scores in between because in this particular case only distributors and wholesalers use the Repository Router.</p>
1-3	Availability of up-to-date technology that supports the solution	10,00%	25,00%					<p>Sources:</p> <ul style="list-style-type: none"> •(Axway, 2011) •(IBM and Matiq, 2008) •(FOSSTRAK, 2010) •(European Commission - TRACES, 2016) •(European Commission - DG HOME, 2016) •(GS1 System Architecture, 2016) •(INSPIRE, 2011) <p>Description:</p> <p>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) currently exist European systems with central repositories.</p> <p>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</p>

(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
								<p>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 is 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.</p> <p>Option B4 also scores low because there are no real references available of supply chain projects establishing such specific synchronisation mechanisms.</p>
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 always is possible a certain level of unavailability.						
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	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						

(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
	and importers							standards, none of the options would cause specific interoperability issues to communicate with the 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 equal, 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 to be interfaced 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.				

(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
2-4	Interoperability with the System for Exchange of Excise Data (SEED)	2,50%	25,00%					Sources: <ul style="list-style-type: none"> •(EMCS SEED, 2016) •(OASIS SOAP, 2007) •Same as criterion A-1
								<p>Description:</p> <p>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.</p> <p>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 reach the highest score.</p>
3	Ease of operation	10,00 %						
				100	75,00	50,00	75,00	
3-1	Impact on the operational processes of the manufacturers and importers	3,33%	33,33%					Sources: <ul style="list-style-type: none"> •Same as criterion A-1
								<p>Description:</p> <p>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.</p> <p>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.</p> <p>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.</p>

(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
								<p>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 because 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.</p> <p>This criterion assumes that the data storage solution publishes standard and open interfaces, such has been elaborated in criterion A-1.</p>
3-2	Impact on the operational processes of the distributors and wholesalers	3,33%	33,33%					<p>Sources:</p> <ul style="list-style-type: none"> •Same as criterion A-1 •Same as criterion 1-2 <p>Description:</p> <p>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.</p> <p>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).</p> <p>Option B1 scores the highest because the reports are sent directly to the data storage solution.</p> <p>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.</p>
3-3	Ease to operate and maintain all the sub-systems involved to implement the whole data	3,33%	33,33%					<p>Sources:</p> <ul style="list-style-type: none"> •Same as criterion 7-1 •Same as criterion 1-1 <p>Description:</p> <p>On one hand, option B1 is a central solution established by an independent third party data storage provider.</p>

(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
	storage solution							<p>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.</p> <p>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.</p> <p>The fact that B3 scores a bit lower is due to the estimated number of solutions involved. As elaborated in criterion 7-1, it is expected that B3 would include more data storage solutions than B2 and B4.</p>
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%					<p>Sources: •(Tanenbaum & Steen, 2006)</p> <p>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.</p> <p>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.</p>
4-2	Ability to ensure data integrity of the system as a whole (i.e. degree of minimising data)	5,00%	50,00%					<p>Sources: •(Rivero & Doorn, 2002) •(Tanenbaum & Steen, 2006)</p> <p>Description:</p>

(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
	inconsistencies)							<p>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.</p> <p>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 previous to the synchronisation to the central repository.</p>
5	System security	10,00 %		 75	 75	 75	 75	
5-1	Guarantee of a secure storage of the data	5,00%	50,00%					<p>Sources:</p> <ul style="list-style-type: none"> •(Rivero & Doorn, 2002) •(Tanenbaum & Steen, 2006) <p>Description: To guarantee a secure storage, the solution should be secured from threats (i.e. interception, interruption, modification and fabrication) and also from attacks.</p> <p>B1 poses the challenge of being a single point of vulnerability. Thus, commercially sensitive information such as trade or products movements may be hacked from this central storage solution. Same challenge could be applied to B4 because there is a central surveillance solution that stores all the data as well.</p> <p>Therefore, having “pure” decentralised database models, B2 and B3, help achieving a better score due to the fact that actually such distribution of solutions minimise the impact that any attack may cause because it is unlikely that will be launched to all the solutions and each distributed</p>

(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
		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 -

(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
								<p>Economic analysis of tobacco products, 2013) •Annex C - Total Consumption of tobacco products as per Member State</p>
		<p>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.</p> <p>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 much higher, 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 costs 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 assuming that the rest of Member States would establish one repository to be shared by three Member States.</p> <p>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, assuming some sort of synergies between groups</p>						

(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
		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 checked in Annex B.						
7-2	Ability to promote market competition to provide the data storage solution	5,00%	50,00%					Sources: •(European Commission - Economic analysis of tobacco products, 2013) •Annex C - Total Consumption of tobacco products as per Member State
		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.						
8	Burden for public authorities	10,00 %						
				100	50	25	75	

(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 public authorities	10,00%	100,00 %					Sources: <ul style="list-style-type: none"> •Cost Analysis •(European Commission - Economic analysis of tobacco products, 2013) •Annex C - Total Consumption of tobacco products as per Member State
<p>Description: The burden for public authorities is based on the costs for public authorities related to approval, monitoring and regularly evaluation of the contracts with the third party data storage provider(s).</p> <p>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.</p> <p>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.</p> <p>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 is also considered the complexity that another central sub-system could imply, as per option B4 with the surveillance solution.</p> <p>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.</p> <p>Further details about the cost estimations, assumptions and what is included</p>								

(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
		can be checked in Annex B.						

Table 2: Data storage model – detailed evaluation of the policy options

7.3. 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	
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. According to the Interim Report I, the maximum length of the unique identifier has been estimated in 161 characters. Nevertheless, the unique identifier sizing could be improved by certain							

(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
									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, master case, 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	

(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
1-1	Ability to adapt the data carrier to the unit packet of all tobacco products.	1.39%	16.67%						Sources: <ul style="list-style-type: none"> •(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 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 identified a certain number of data carriers able to be printed or affixed in 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-criteria 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	1.39%	16.67%						Sources: <ul style="list-style-type: none"> •(GS1 Barcodes, 2017)

(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
	aggregation packaging levels.								<ul style="list-style-type: none"> •(GS1 DataMatrix, 2016) •(securPharm, 2016) •(California State Board of Pharmacy, 2013) •(everis, 2016)
<p>Description:</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>									

(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
1-3	Impact generated by the printing or affixing activities on the manufacturer and importer production processes.	1.39%	16.67%						Sources: •(Booz Hallen Hamilton, 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: <ul style="list-style-type: none"> • 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	1.39%	16.67%						Sources: •(Booz Hallen Hamilton, 2014) •(McFarlane & Sheffi,

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C5: Free system allowing any existing approved data carrier

ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
	at wholesalers and distributors.								2003) •(EFPIA - European Federation of Pharmaceutical Industries and Associations, 2015) •(accenture, 2008)
<p>Description:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 renovated.</p> <p>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.</p> <p>The option C2 is the most favourable because it allows only a single data carrier and also contemplates the optional addition of data carriers.</p>									
1-5	Availability of different	1.39%	16.67%						Sources: •(Beil, 2009)

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ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
	suppliers (with regard to third-party SW/HW components, external support, and external services).								<p>Description:</p> <p>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.</p> <p>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.</p> <p>The options C1 and C2 obtain the highest score because they only consider a data carrier.</p> <p>Options C3 and C4 are more restrictive in regards to the availability of different suppliers because the number of allowed data carrier increases.</p> <p>The option C5 is the least favourable because it considers a higher number of allowed data carriers.</p>
1-6	Ability to adapt to quality control activities.	1.39%	16.67%						<p>Sources:</p> <ul style="list-style-type: none"> •(GS1 2D Barcode, 2015) •(GSM Barcoding, 2016) •(The Institute of Internal Auditors, 2016)
				<p>Description:</p> <p>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.</p> <p>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.</p> <p>The scorings for this sub-criterion are similar to 1-5 and they depend on the number of allowed data carriers.</p> <p>The options C1 and C2 obtain the highest score because they only consider a data carrier.</p>					

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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
									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	
2-1	Full interoperability with the systems of key users (i.e. competent national and European authorities).	2.78%	33.33%						Sources: •(ISO/IEC Standardization vocabulary, 2005) •(ITU, 2012) •(McCathie, 2004) •(Su, Chu, Prabhu, & Gadh, 2007) •(Copenhagen University College of Engineering, 2008)
				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: <ul style="list-style-type: none"> • 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					

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C5: Free system allowing any existing approved data carrier

ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
									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.
2-2	Organizational interoperability - manufacturer & importer equipment.	2.78%	33.33%						Sources: •(McFarlane & Sheffi, 2003)
				Description: As it was stated for the sub-criteria 2-1, to support the interoperability between systems two aspects must be taken into account: <ul style="list-style-type: none"> • 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.					
2-3	Organizational interoperability - wholesaler & distributor equipment.	2.78%	33.33%						Sources: •(McCathie, 2004) •(Su, Chu, Prabhu, & Gadh, 2007) •(Copenhagen University College of

(C) Allowed Data Carriers

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C5: Free system allowing any existing approved data carrier

ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
									Engineering, 2008)
		<p>Description:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>The option C3 is more restricted than C4 because it does not contemplate the optional addition of data carriers.</p> <p>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.</p>							
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%						<p>Source:</p> <ul style="list-style-type: none"> •(O'Connor, Haque, & al., 2012) •(Ivantysynova, 2008)
		<p>Description:</p> <p>The impact on the operation depends on the type of new process to be</p>							

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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
									<p>implemented. These processes are integrated in the production line and require activities of maintenance and surveillance.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>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.</p>
3-2	Impact on the operational processes of the wholesalers/ distributors/ transporters.	2.08%	25.00%						<p>Source:</p> <ul style="list-style-type: none"> •2D symbols in distribution and logistics GS1 (2015) •(McFarlane & Sheffi, 2003) •US healthcare bar code scanner acquisition criteria – GS1 Healthcare
				<p>Description:</p> <p>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).</p> <p>The accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used.</p> <p>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.</p>					

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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
									<p>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).</p> <p>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.</p> <p>Option C3 is more restricted than C4 because it does not contemplates the optional addition of data carriers.</p> <p>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.</p>
3-3	Impact on printing or affixing performance.	2.08%	25.00%						<p>Source: •(Bonaccorsi, 2012)</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
3-4	Impact on scanning speed	2.08%	25.00%						<p>Source: •(National Center for</p>

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ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
	and reliability.								Immunization and Respiratory Diseases Immunization Services Division, 2014) <ul style="list-style-type: none"> •(GS1, 2010)
		<p>Description:</p> <p>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.</p> <p>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.</p> <p>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 not obligation of including additional data carriers.</p> <p>The options C1 and C2 are less favourable because they only consider one data carrier, which increases the impact in the production activities.</p>							
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: <ul style="list-style-type: none"> •(GS1 Healthcare US, 2014) • (GS1, 2015) •(GS1 2D Barcode, 2015)
		<p>Description:</p> <p>The consistency of the data carriers depends on their internal structure</p>							

(C) Allowed Data Carriers

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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
				<p>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.</p> <p>The generation of the unique identifier is going to be based in open standards in order to facilitate the interoperability between systems, conditioning the selection of data carriers.</p> <p>The production identifier enables to distinguish 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.</p> <p>Although, the accomplishment of the sub-criteria is not inherent to the number of data carriers itself but to the type of data carriers used.</p> <p>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.</p> <p>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.</p> <p>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.</p>					
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%						<p>Source:</p> <ul style="list-style-type: none"> •(GS1 DataMatrix, 2016) •(Peris-Lopez & al., 2006) •(McCathie, 2004)
			Description:	<p>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</p>					

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ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
									<p>the selected data carriers.</p> <p>In addition, the literature has shown some types of data carriers that may include security features, reducing the risk of being falsified.</p> <p>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.</p> <p>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.</p> <p>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-criteria.</p> <p>The option C5 obtains the lowest score because it allows the use of any approved data carrier, increasing the risk associated to security features.</p>
6	Potential of reducing illicit trade	25%	100%						
				50	100	100	100	50	
6-1	Potential of reducing illicit trade	25.00%	100.00%						<p>Source:</p> <ul style="list-style-type: none"> •(European Commission - Feasibility Study, 2015) •(National Center for Chronic Disease Prevention and Health Promotion, 2016)
				<p>Description:</p> <p>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.</p> <p>This aim is related with the efficiency of the system, and the combination of sub-criterions previously stated, such as system</p>					

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ID	Evaluation parameters	Global Weight	Element Weight	C1	C2	C3	C4	C5	Comments
				<p>interoperability and system security.</p> <p>For this purpose, it is considered that the types of allowed data carriers will challenge the objective of reducing illicit trade.</p> <p>The option C2 obtains the highest score because it only allow one data carrier, in turn implying the system is more efficient and enables the easier identification of potential irregularities, therefore limiting the risk.</p> <p>Options C3 and C4 (a range of approximately four types of data carrier per identification level) also accomplish with this sub-criteria because the short variety of allowed data carriers facilitates the correct selection.</p> <p>Despite enabling the use of only a 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.</p> <p>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.</p>					
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%						<p>Source:</p> <ul style="list-style-type: none"> •(European Commission - Feasibility Study, 2015) •(European Commission - Inception Impact Assessment TPD, 2016)
		<p>Description: The economic impact of the allowed data carriers on manufacturers and importers depends on the cost associated to adapt their production lines</p>							

(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
									<p>to the printing and affixing activities. It is assumed that every production line is going to print only a data carrier, and for the purpose of this study most of the economic operators have to adapt their lines.</p> <p>As it was stated for the sub-criteria, the cost incurred by the manufacturer depends on which of the three different scenarios is considered:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>In base to all these factors, the option C5 obtains the highest score because the ability to select the data carrier in a free system that better adapts to the production needs.</p> <p>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).</p> <p>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.</p>
7-2	Impact of the allowed data carriers on wholesalers, distributors & transporters	4.16%	33.33%						<p>Source:</p> <ul style="list-style-type: none"> •(European Commission - Feasibility Study, 2015) •(GS1 Healthcare, 2009)
		<p>Description: The economic impact of the allowed data carriers on wholesalers, distributor and transporters depends on the cost associated to the</p>							

(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
		<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The worst alternative in terms of burden for wholesalers, distributors and transporters is the option C5 because it considers any approved data carrier. Then, they have to adapt to the data carriers used in the items provided by their suppliers.</p>							
7-3	Ability to promote market competition	4.16%	33.33%						<p>Source:</p> <ul style="list-style-type: none"> •(Council of economic advisers issue brief, 2016) •(Beck, Grajek, & Wey, 2005) •(Milne, 2013)
		<p>Description:</p> <p>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.</p> <p>Besides, the competition can lead to innovation and integration in the</p>							

(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
				<p>group of allowed data carrier of new types of technologies that could increase the efficiency of the system and the ease of operation.</p> <p>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.</p> <p>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.</p>					
8	Administrative/ financial burden for public authorities	12.5%	100%	 75	 75	 50	 50	 25	
8-1	Impact of the allowed data carriers on the public authorities	12.50%	100.00%						Sources: •(European Commission - Feasibility Study, 2015) •(GS1 Healthcare, 2009)
		<p>Description:</p> <p>The economic burden for public authorities depends on the cost of the necessary 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.</p> <p>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.</p> <p>The options C1 and C2 obtain the highest score because they only allow</p>							

(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
									<p>one data carrier, facilitating the operations of inspection.</p> <p>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.</p> <p>The option that obtains the lowest score is C5 because it allows any approved data carrier, representing a higher cost associated to equipment.</p>

Table 3: Allowed data carriers – detailed evaluation of the policy options

7.4. 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: <ul style="list-style-type: none"> •(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 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 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: <ul style="list-style-type: none"> •(ISO/IEC 19987:2015 EPCIS, 2016) (GS1 System Architecture, 2016) •(WHO - FCTC, 2010) •(Rx-360 Consortium,

(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
							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: <ul style="list-style-type: none"> •(Gustafsson, 2007) •(European Commission - 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 tasks, 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 a too low 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, synchronize and process the data prior being effective and ready to be used by the competent authorities.					

(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
1-2	Complexity on managing the volume of data on the Local Buffer	4.17%	50.00%				Sources: •(Gustafsson, 2007) •(Lindström & Elbushra, 2014) (Srivastava, Shankar, & Tiwari, 2012)
		Description: Prior being reported to the tracking and tracing system, the data is retained in a 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 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 option 1, which can be very small and less demanding, scores to low level of complexity, whereas the other options, as the data retention time increases, the operation complexity also increases, reflected on 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 one week time lag, the volume of data captured during this interval can be 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 option 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 to					

(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
		interoperate with the actual economic operator’s information systems, implying a lower impact than option D1, although a substantial impact is not discarded.					
2-2	Ability to interoperate 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 - Inception Impact Assessment TPD, 2016) •(European Commission - TAXUD, 2006)
2-4	Interoperability with the System for Exchange of Excise Data (SEED)	2.08%	25.00%				Sources: •(European Commission - TAXUD, 2006)
		Description: All three options offer full interoperability with the systems of the key users. Regardless of which option is chosen, the relationship between the national 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, it can be foreseen the next step, when a key user’s system may require to integrate with the tracking and tracing system, then at this point, the allowed delay may impact on the interoperability if the key 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), only possible to be accomplished by the near real-time, therefore option D1, due to its broader level of data freshness achievement, in a					

(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
		preliminary approach, is closer to be the optimal solution, at the same time, option D1 can also attend 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, &

(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
							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) • (Veregin, 2005)
	Description: Option D2 and mostly option D3 poses a problem on the tracking and tracing system when regarding to detect 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						

(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
		<p>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.</p>					
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)
		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 a 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 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 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)

(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: <ul style="list-style-type: none"> •Critical analysis •(European Commission - 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, which indeed, for example, it is possible to become extremely late in case an action must be taken prior a product						

(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
		being delivered.					
7	Burden for economic stakeholders	12.50 %					
		6.25%	50.00%				Sources: <ul style="list-style-type: none"> •Cost Analysis •(Eurostat, 2013) •(European Commission - Feasibility Study, 2015)
7-1	Impact on the cost for the operational processes to perform the Data Compilation of movements and the information about transactions.	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 local storage regarding the Data Retention prior being reported to the system.	6.25%	50.00%				Sources: <ul style="list-style-type: none"> •Cost Analysis •(Eurostat, 2013) •(European Commission - Feasibility Study, 2015)
		Description: Prior being reported to the tracking and tracing system, the data is retained in a 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 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					

(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
		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 public 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 public authorities					

Table 4: Allowed delays in reporting events – detailed evaluation of the policy options

7.5. 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	
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 - Inception Impact Assessment TPD, 2016) (everis, 2016)
		<p>For S1, affixing was the method chosen 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)</p> <p>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:</p> <ol style="list-style-type: none"> 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); 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) 					

(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
		<p>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)</p> <p>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)</p> <p>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)</p> <p>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'.</p> <p>For S3, with option 'Mixed solution' the choice lies between affixing or printing or integrating through a different method.</p> <p>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.).</p>					
A-2	Ability to combine visible and invisible elements on the security feature	0%	33.3%				(European Commission - Feasibility Study, 2015) (everis, 2016)
		<p>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 number of overt (i.e. visible), covert (i.e. invisible) and forensic security elements that can be combined to</p>					

(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
		<p>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)</p> <p>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).</p> <p>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)</p> <p>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)</p> <p>There are also some security features specifically related with direct printing techniques, such as intaglio printing, flexography, guilloche, and micro printing.</p> <p>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)</p> <p>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.</p>					
A-3	Guarantee that the security feature is tamper proof and irremovable	0%	33.3%				(European Commission - Feasibility Study, 2015)
		<p>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</p>					

(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
							<p>Study (European Commission - Feasibility Study, 2015, p. 75)</p> <p>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.</p> <p>There are also specific methods to add tamper resistance to an affixed security feature, such as:</p> <ol style="list-style-type: none"> 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 Feasibility Study (European Commission - Feasibility Study, 2015, p. 75) <p>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)</p> <p>In opposition, concerning S2, printing or integrating through a different method guarantees that the security feature is physically printed or</p>

(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
		<p>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)</p> <p>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)</p>					
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)
		<p>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.</p> <p>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)</p> <p>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)</p> <p>Regarding S2, installation of equipment to print or integrate a security</p>					

(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
		<p>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.</p> <p>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)</p> <p>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.</p>					
1-2	<p>Ability to outsource the production of security features with a minimal impact on the manufacturers' production process</p>	4.17%	50.0%				<p>(European Commission - Feasibility Study, 2015) (Member States representatives, 2016)</p>
		<p>Concerning S1, and where applicable, the national 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)</p> <p>This way, security printers are used to handle sensitive material like papers, security elements, security inks, and semi-finished and finished goods.</p> <p>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)</p> <p>In this model, the security features would then be shipped to the tobacco manufacturers that would affix them onto unit packets of tobacco products.</p> <p>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.</p>					

(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
		<p>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.</p> <p>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.</p> <p>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)</p> <p>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).</p> <p>This way, the tobacco manufacturers can work to minimise the impact on their production process.</p>					
2	Interoperability (with key users' and other company's systems)	8.33%	N/A				
				100	100	100	
2-1	Interoperability between national authorities and their testing labs and the testing capabilities provided by OLAF - JRC	2.78%	33.3%				(Member States representatives, 2016)
		<p>All options guarantee the same level of interoperability between the national authorities and OLAF - JRC, as the interoperability is evaluated at security feature level, and not through its method of application.</p> <p>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 independently from the industry.</p>					

(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
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)
		<p>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.</p> <p>This being said, there are multiple ways to authenticate a security feature by the public authorities, and whichever security elements are implemented, they need to be given access to them:</p> <ol style="list-style-type: none"> 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)
		<p>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</p>					

(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
		<p>identifier as an overt security element.</p> <p>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)</p> <p>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.</p>					
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)
		<p>Regarding S1, an affixed security feature has the advantage that the practice of application of stamps during the manufacturing process is known and generally accepted within the industry.</p> <p>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).</p> <p>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)</p> <p>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).</p> <p>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 ,</p>					

(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
		<p>Feasibility Study (European Commission - Feasibility Study, 2015, p. 244)</p> <p>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)</p> <p>On S3, regardless the method chosen, there is always the possibility to generate an impact on the operational processes of the manufacturers.</p> <p>The possibility of choosing the method of application brings an additional layer of flexibility which enables the manufacturers to minimise the impacts generated.</p>					
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)
		<p>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)</p> <p>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.</p> <p>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</p>					

(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
		<p>the packaging material (e.g. fingerprinting) although it is considered hard to assure the integrity of the packs.</p> <p>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].</p>					
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)
		<p>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:</p> <ol style="list-style-type: none"> 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. 					

(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. 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 trade	25.00 %	N/A	 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					

(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
		<p>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)</p> <p>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</p> <p>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)</p> <p>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)</p>					
7	Burden for economic stakeholders	12.50 %	N/A	 100	 25	 100	
7-1	Burden for economic stakeholders	12.50 %	100%				N/A
		<p>The options (S1) and (S3) have a cost of approximately 15 M€ per year and they do not have a significant difference between them.</p> <p>With a cost 75 M€/year, option S2 has the highest burden for economic stakeholders, and so, the lowest score.</p> <p>The detailed cost analysis can be found on Annex B. Detailed Calculation of the Costs.</p>					
8	Burden for public authorities	12.50 %	N/A	 100	 100	 100	
8-1	Burden for public	12.50 %	100%				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
	authorities	<p>No burden on public authorities is considered, as all the controls performed by the public authorities are considered under A. Governance model.</p> <p>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.</p>					

Table 5: *Method of adding a security feature – detailed evaluation of the policy options*

ANNEX 6 – COST-BENEFIT ANALYSIS

Part of Everis Report

5.1. 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 section is comprised of four main parts that assess the viability of the project implementation:

- Benefit and cost analysis:
 - It analyses the benefit streams, the investment, and ongoing costs associated to the execution of the project. Besides it compares the inflows and outflows for the project lifetime.
 - 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).
 - The cost assessment describes the capital and operational expenditures for the project lifetime.
- 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.

5.1.1. Benefit & cost analysis

5.1.1.1. Benefit assessment

Illicit tobacco trade has been estimated to account at 11.26% (European Commission - TPD Inception Impact Assessment, 2016) of the total consumption of tobacco products. Implementing effective measures to control and fight against illicit trade will contribute to reducing the total consumption. The effect of this reduction is expected to be threefold (Reed, 2010):

- Some smokers will smoke less;
- Others will stop smoking altogether; and
- Smoking take-up may also decline, increasing the number of non-smokers.

Additionally, the benefits associated to the effective implementation of the proposed measures can be classified by their nature:

- Economic benefits;
- Social and environmental benefits.

All the calculations presented in this study have been detailed by country in the annex C for each Member State of the EU28.

5.1.1.1.1. Economic benefits

The economic benefits are defined as the net income generated as the result of the implementation of the proposed measures. In this sense, the solution revenues and benefits are analysed using two main quantitative factors:

- Revenues from increase in legal sales
 - For each percentage of the current tobacco market that is illicit, a potential tax loss amount can be calculated.
- Other socio-economic benefits
 - Reduction in cost associated to public health savings.
 - Benefits derived from increase in productivity.

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 total consumption of manufactured cigarette in the 28 Member States to be

27.49 billion of units packets (assuming an unit packet contains an average of 20 cigarettes), while the illicit consumption is rated as 3,096 million of unit packets.

Consumption breakdown		
Legal Consumption <i>(Millions of unit packets – Total EU28)</i>	(A)	24,395.80
Illicit Consumption <i>(Millions of unit packets – Total EU28)</i>	(B)	3,096.01
Total Consumption <i>(Millions of unit packets – Total EU28)</i>	(C) = (A) + (B)	27,491.81
% Illicit Consumption <i>(% - Total EU28)</i>	(D) = (B) / (C)	11.26%
Source: (A): (European Commission - TPD Inception Impact Assessment, 2016) (B): (World Lung Foundation, 2015)		

Table 1: Consumption breakdown of tobacco products

The report further divides the illicit consumption into illicit whites, counterfeit, and other counterfeit and contraband (C&C), which was assumed to be 100% contraband for the purpose of the calculations.

Illicit Consumption		
Percentage of Illicit Whites <i>(Average % for EU28)</i>	(E)	34.63%
Percentage of Counterfeit <i>(Average % for EU28)</i>	(F)	6.78%
Percentage of Contraband <i>(Average % for EU28)</i>	(G)	58.59%
Illicit Whites Consumption <i>(Millions of unit packets – Total EU28)</i>	(H) = (B) · (E)	1,025.33
Counterfeit Consumption <i>(Millions of unit packets – Total EU28)</i>	(I) = (B) · (F)	248.62
Contraband Consumption <i>(Millions of unit packets – Total EU28)</i>	(J) = (B) · (G)	1,822.06
Source: (E), (F), (G): (Transcrime, Joint Research Centre on Transnational Crime, 2015)		

Table 2: Illicit consumption of tobacco products

The effective implementation of the proposed measures aims for a reduction of illicit trade to the order of 30% for contraband (European Commission - TPD Inception Impact Assessment, 2016), 10% for counterfeit, and 10% for illicit whites (European Commission - Feasibility Study, 2015), and this will serve as our baseline. 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 I		
Reduction in consumption of Illicit Whites <i>(Millions of unit packets – Total EU28)</i>	(K) = (H) · 10%	102.53
Reduction in consumption of Counterfeit <i>(Millions of unit packets – Total EU28)</i>	(L) = (I) · 10%	24.86
Reduction in consumption of Contraband <i>(Millions of unit packets – Total EU28)</i>	(M) = (J) · 30%	546.62
Reduction in illicit consumption <i>(Millions of unit packets – Total EU28)</i>	(N) = (K) + (L) + (M)	674.01
Percentage of reduction in Illicit Trade <i>(%– Total EU28)</i>	(O) = (N) / (B)	21.77%
Percentage of reduction in Total Consumption <i>(%– Total EU28)</i>	(P) = (N) / (C)	2.45%

Table 3: Estimated impact on illicit trade reduction (I)

Assuming the baseline values, the solution can produce a reduction in illicit trade with a total impact on the tobacco products market of 674.01 million unit packs, representing a 2.45% reduction in total consumption.

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

- An increase of sales in the legal market; and/or
- A portion of smokers that 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. Then three groups of countries have been identified according their GDP. The specific calculations by country are detailed in Annex C.

- Countries with GDP lower than 80 (-20% over the average EU28): Price elasticity = -0.5
- Countries with GDP between 80 and 120 (between $\pm 20\%$ of the average EU28): Price elasticity = -0.4
- Countries with GDP higher than 120 (+20% over the average EU28): Price elasticity = -0.3

The specific calculations by country are detailed in the Annex C, where the average price elasticity for the EU28 has been estimated at -0.41.

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).

In addition, the consumption of tobacco products can be modelled by using a double-log function, where it is included the influence of external variables such as price (Statistics & Economic Research Branch, 2015) (Huang, Yang, & Hwang, 2004) (Conniffe, 1995).

Thus, the variation in consumption (%) due to the increment in the prices of tobacco products is presented in the annex C, and it is estimated by the following formula (World Bank, 2016).

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

According to the value of -0.41, as the average price elasticity for the EU28, and given an increase of the price of 100%, we can assume that:

- 75.15% of illicit tobacco purchasers would now purchase legitimate tobacco products.
- 24.85% of illicit tobacco purchasers would now decide to reduce their consumption, or even quit smoking.

• Estimated impact on illicit trade reduction II		
GDP per capita in PPS	(Q)	100
Price elasticity	(R)	-0.41
Increase in the price of tobacco products	-	100%
Percentage of consumers that would now decide to reduce their consumption or even quit smoking (Average % for EU28)	(S) = function of (R)	24.85%
Percentage of consumers that would now purchase legitimate tobacco products (Average % for EU28)	(T) = 100% - (S)	75.15%
Reduction in Total Consumption (Millions of unit packets – Total EU28)	(U) = (N) · (S)	164.05
Increase in Legitimate Consumption (Millions of unit packets – Total EU28)	(V) = (N) · (T)	509.97
Source: (Q): (Eurostat, 2016)		

Table 4: Estimated impact on illicit trade reduction (II)

Revenues from increase in legal sales

One of the expected revenues from the implementation of the solution is that the increase in legal tobacco sales will generate an increase in revenues (VAT, excise duty, EO's revenue).

Estimated impact on illicit trade reduction		
Price of a 20 cigarette pack of the most sold brand (Average price for EU28)	(W)	4.38 €
Average VAT (Average % for EU28)	(X)	21.50%
Excise duties as % of the price (Average % for EU28)	(Y)	57.68%
EO's revenue as % of the price	(Z) = 100% - (X) -	20.82%

<i>(Average % for EU28)</i>	(Y)	
Impact on VAT <i>(Millions of Euros – Total EU28)</i>	(A') = (V) · (W) · (X)	528.84 M€
Impact on excise duty <i>(Millions of Euros – Total EU28)</i>	(B') = (V) · (W) · (Y)	1,500.13 M€
Impact on EO's revenue tax <i>(Millions of Euros – Total EU28)</i>	(C') = (V) · (W) · (Z)	525.47 M€
Source: (W): (Transcrime, Joint Research Centre on Transnational Crime, 2015) (X): (European Commission - Taxation and Consumer Union, 2016) (Y): (European Commission - Excise duty tables, 2016)		

Table 5: Estimated impact on illicit trade reduction (III)

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

- 528.84 million euros as new tax revenues from VAT;
- 1,500.47 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.

Other socio-economic benefits

Additionally, the reduction of consumption generates different economic impacts on society. The main positive impact is the reduction in healthcare expenditure.

Apart from improved public health, reduced tobacco consumption will also lead to lower health care costs and improved productivity due to fewer cases of absenteeism and premature retirement. Decreased on-the-job productivity and employee absence, because of smoking related diseases, result in an additional cost factor to employers. Absenteeism costs are calculated by using the “lost wages method” (based on the average daily earnings rate for employed persons) – the most frequently used method to measure these costs.

Annex C shows how the reduction in tobacco consumption is linearly correlated with the overall benefits for governments and society. These socio-economic benefits can be estimated with the following equations:

$$\begin{aligned} & \text{Decrease in healthcare expenditure (M€)} \\ & = \text{Coefficient}_{\text{Healthcare}} \cdot \% \text{Reduction tobacco consumption} \end{aligned}$$

$$\begin{aligned} & \text{Increased productivity (M€)} \\ & = \text{Coefficient}_{\text{Productivity}} \cdot \% \text{Reduction tobacco consumption} \end{aligned}$$

Combining these values with the reduction in consumption, the result is presented below.

Estimated socio-economic benefits		
Healthcare expenditure coefficient	(D')	25,300
Increased productivity coefficient	(E')	8,300
Decrease in healthcare expenditure (Millions of Euros – Total EU28)	(F') = (D') · (S) · (P)	154.03 M€
Increased productivity (Millions of Euros – Total EU28)	(G') = (E') · (S) · (P)	50.53 M€
Source: (D') (E'): (European Commission - TPD Impact Assessment, 2012)		

Table 6: Estimated socio-economic benefits

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

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

Overall economic benefits

As overall quantitative results, the baseline reduction of illicit trade (30% for contraband, 10% for counterfeit, and 10% for illicit whites) is expected to generate 2,759.01 million euros:

- 2,554.45 million euros in revenues from an increase in legal sales;
- 204.56 million euros in other socio-economic benefits.

However, it would not be realistic to assume that all this revenue will be achieved at the very beginning of the implementation of the system. We estimate that the 30/10/10 results in the reduction of illicit trade will be achieved after six years of system operation (NASA Handbook, 2010) (Aitchison & Campbell, 1976):

	2018	2019	2020	2021	2022	2023	2024
Estimated impact on contraband reduction	0	2.9%	8.6%	20.2%	25.9%	28.8%	30.0%
Estimated impact on counterfeit reduction	0	1.0%	2.9%	6.7%	8.6%	9.6%	10.0%
Estimated impact on illicit whites reduction	0	1.0%	2.9%	6.7%	8.6%	9.6%	10.0%

Table 7: Evolution of the impact on illicit trade reduction

Replicating the above analysis with the adjusted impacts, we conclude that the expected annualised revenues can be summarised as follows (in millions of euros):

	2018	2019	2020	2021	2022	2023	2024
Revenues from increase in legal sales	-	250.33 M€	735.68 M€	1,716.59 M€	2,201.93 M€	2,452.28 M€	2,554.45 M€
Other socio-economic benefits	-	20.05 M€	58.91 M€	137.46 M€	176.33 M€	196.38 M€	204.56 M€
Total revenue increment	-	270.38 M€	794.59 M€	1,854.05 M€	2,378.27 M€	2,648.66 M€	2,759.01 M€

Table 8: Evolution of the economic inflows

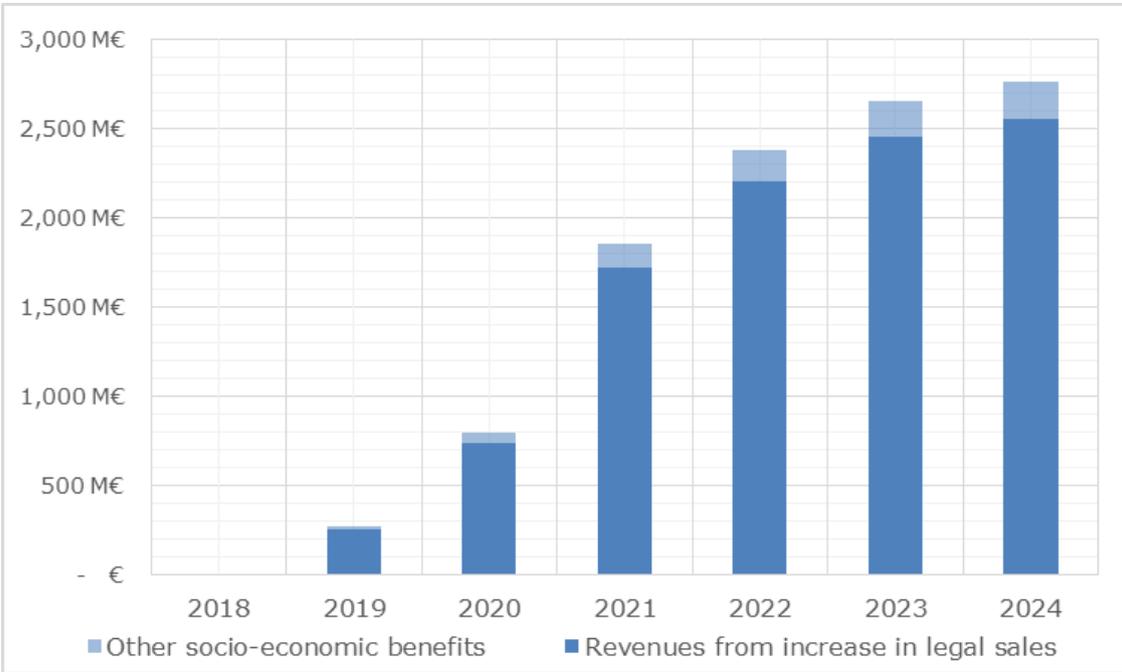


Figure 1: Overall revenues of the solution (million €)

5.1.1.1.2. Social and environmental benefits

On the other hand, the reduction, or quitting of smoking, produces several social and environmental benefits to society. The main positive impact in this regard is the improvement of public health. People who do not smoke or reduce their consumption of tobacco products, until eventually quitting smoking, are healthier and live significantly longer. These benefits have been grouped in three categories:

- People who reduce or quit smoking
- Reduction of premature mortality cost due to smoking
- Other social and environmental benefits

People who reduce or quit smoking

It is possible to quantify the reduction in tobacco products consumption in terms of people. For this calculation, the number of people over 15 years of age in the 28 Member States has been isolated (Eurostat, 2015) (429.1 million people), and current smoking rate of tobacco products (Transcrime, Joint Research Centre on Transnational Crime, 2015).

Considering an overall reduction in illicit trade of 2.45%, and that 24.85% of the current illicit tobacco purchasers would now decide to reduce their consumption, or even quit smoking, the number of people who reduce or quit smoking can be modelled. This assumes that the reduction in tobacco consumption directly impacts the current number of smokers.

People who will reduce or quit smoking		
Total population <i>(Millions of people – Total EU28)</i>	(H')	508.45
Population above 15 years old <i>(Millions of people – Total EU28)</i>	(I')	429.11
Current smoking rate of tobacco <i>(Average % for EU28)</i>	(J')	25.71%
Number of people who will reduce or quit smoking <i>(Millions of people – Total EU28)</i>	(K') = (P) · (S) · (I') · (J')	0.712
Source: (H') (I'): (Eurostat, 2015) (J'): (Eurobarometer, 2017)		

Table 9: Summary of the social benefits I

Reduction of premature mortality due to smoking

It has been demonstrated that smoking harms nearly every organ of the human body, causing a wide variety of diseases (US Department of Health and Human Services, 2004) Several of these have been identified as fatal, while other are chronic. Another study has estimated that, on average, smokers who die as a result of their tobacco consumption die 14 years earlier than people who never smoked (Peto, Lopez, Boreham, & Thun, 2011).

The TPD Impact Assessment (European Commission - TPD Impact Assessment, 2012) estimates the value of one life year to be 52,000€. The total number of life years lost per country (DG SANCO, 2008) has been 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.

Reduction of premature mortality due to smoking		
Total YLL due to smoking	(L')	9,936,791
Reduction in YLL by the effective	(M') = (L') ·	60,274

implementation of the proposed measures	(P) · (S)	
Monetary value of loss (Millions of Euros – Total EU28)	(N') = (M') · 52,000€	3,134 M€
Source: (L'): (DG SANCO, 2008)		

Table 10: Summary of the social benefits II

Other social and environmental benefits

Others costs to society and environment related to tobacco consumption will also be reduced (ASH, 2015):

- Cost of fires caused by smokers' materials (cigarettes and other smoking materials are the primary cause of fatal accidental fires in the home);
- Improvements in the distribution chain after implementing the measures associated to the tracking and tracing system of tobacco products.
- Reducing illicit tobacco trade would reduce the financing of these criminal groups. It has been proven that illicit trade of tobacco products fuels transnational crime, corruption and terrorism (US Department of State, 2015). Organised criminal groups, including those with ties to terrorist organisations are engaged in illegal trafficking in alcohol and tobacco products, including counterfeit tobacco products (Interpol, 2014).

5.1.1.2. Cost assessment

The cost analysis was performed as part of the evaluation of each policy option. The costs of each specific policy option have already been presented in Chapter 4, and detailed in Annex B.

In this section, a summarised view of the annualised costs of the solution is presented, taking into account both “one-off” costs and “recurring” costs. This enables a comparison of the revenues generated by the implementation of the system.

	A3	B4	C4	D1	S3
CAPEX	96.36 M€	19.01 M€	167.59 M€	38.99 M€	- €
OPEX	26.94 M€	7.29 M€	9.66 M€	42.17 M€	14.89 M€

Table 11: Overall costs of the solution

The CAPEX corresponding to the implementation of the system for cigarettes and RYO is estimated for 2018, while the CAPEX for the implementation of the system for other tobacco

products is foreseen for 2023. The OPEX starts as of May 2019 for tobacco and RYO and May 2024 for other tobacco products (millions of euros):

	2018	2019	2020	2021	2022	2023	2024
CAPEX - Governance model	92.56	-	-	-	-	3.78	-
CAPEX - Data storage model	18.26	-	-	-	-	0.75	-
CAPEX - Allowed data carriers	160.98	-	-	-	-	6.59	-
CAPEX - Allowed delays in reporting events	37.45	-	-	-	-	1.53	-
CAPEX - Method of adding a security feature	-	-	-	-	-	-	-
CAPEX - TOTAL	309.26	-	-	-	-	12.65	-
OPEX - Governance model	-	17.25	25.88	25.88	25.88	25.88	26.58
OPEX - Data storage model	-	4.66	7.00	7.00	7.00	7.00	7.19
OPEX - Allowed data carriers	-	6.18	9.28	9.28	9.28	9.28	9.53
OPEX - Allowed delays in reporting events	-	27.00	40.51	40.51	40.51	40.51	41.61
OPEX - Method of adding a security feature	-	9.53	14.30	14.30	14.30	14.30	14.69
OPEX - TOTAL	-	64.64¹	96.97	96.97	96.97	96.97	99.61

Table 12: Detailed CAPEX and OPEX

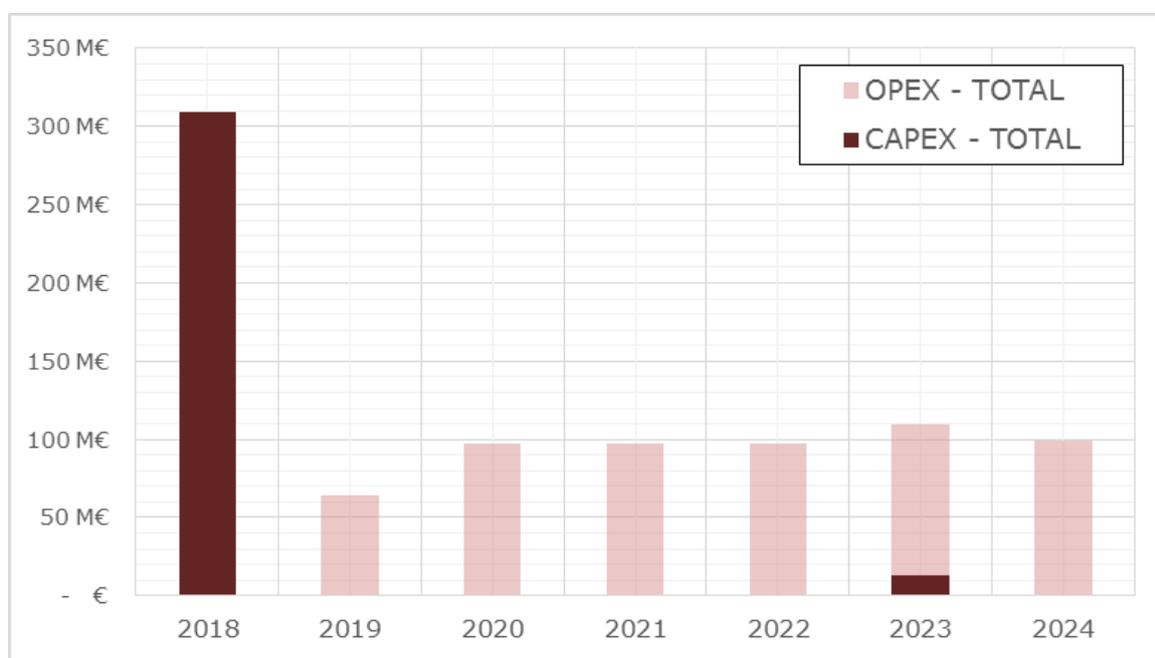


Figure 2: CAPEX and OPEX Costs distributed per year (million €)

¹ The OPEX for 2019 are influenced by the fact of the measure is effective in May of that year.

The detail of the costs presented here can be found in Annex B (Detailed Calculation of the Costs).

When analysing the detailed costs, it is necessary to take into account that for the evaluation of the alternative policy options, all costs related with each option were taken into account without looking at synergies with the other decision points.

5.1.1.3. Evaluation

The costs of the solution are considerable, but it is important to notice that the solution has the potential to generate a large amount of revenue for Member States, economic operators, and EU citizens.

The following figure shows the combination of revenues and costs previously calculated.

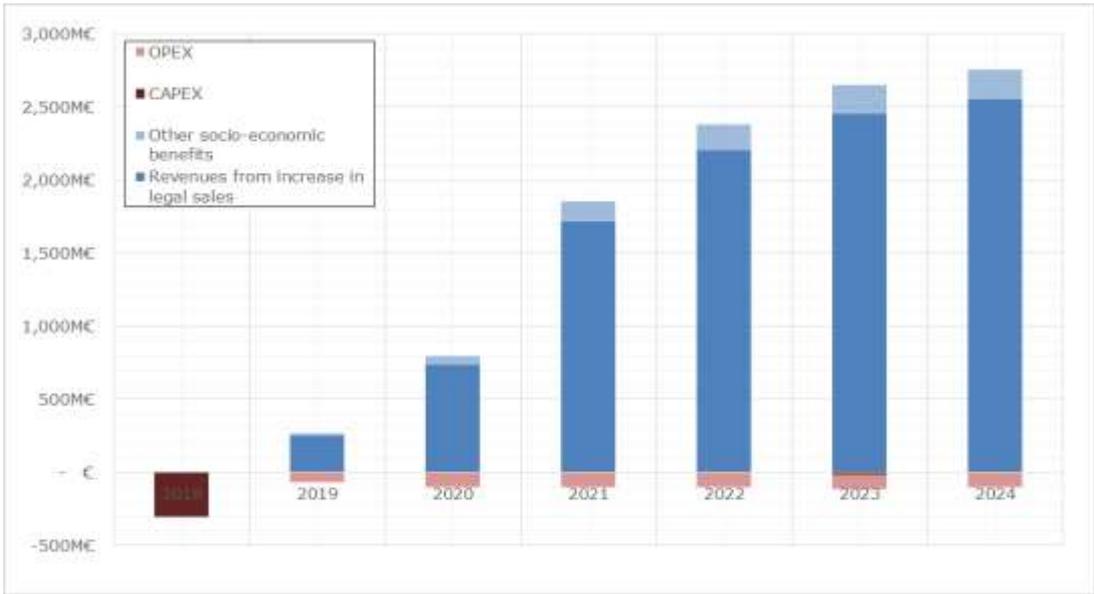


Figure 3: Comparison between the revenues and the costs of the solution (million €)

In our model, the expected revenues largely surpass the expected costs to implement the solution (CAPEX) and the recurrent costs to operate it (OPEX). The revenues are quantified in terms of revenues from the increase in legal sales (new tax revenues and new revenues for economic operators involved in the value chain of tobacco products) and other socio-economic revenues (lower health care spending and new revenues from increased productivity).

These values are based on a set of assumptions and lack real-life testing, but they are an important baseline to evaluate the implementation of the solution. Many other studies (Reed, 2010) (Joossens, Merriman, Ross, & Raw, 2010) reinforce the idea that the revenues of implementing systems that help to eliminate global illicit trade surpass the costs of the implantation of such systems.

Some deviations can occur when implementing the solution, but it is equally true that economies of scale can be attained that may reduce some of the costs modelled. In the end, the solution has the potential to generate considerable benefits over the years, even if the economic operators must make a large initial investment.

5.1.2. 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€
<i>The inflows and outflows were obtained from the revenue-cost assessment</i>			

Table 13: 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.

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

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.

5.1.3. 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
<i>Revenue-based variables</i>	
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
<i>Cost-based variables</i>	
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 14: 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 $\pm 1\%$ 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	0.19%	Not critical

reduction		
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 15: 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	
<i>Revenue-based variables</i>		
Total consumption	Maximum decrease before NPV equals 0	91%

Average price of unit packet	Maximum decrease before NPV equals 0	91%
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%
<i>Cost-based variables</i>		
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 16: 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 $\pm 20\%$ 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 17: 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 $\pm 20\%$ in the revenue-related variables.

Effect of the policy options in the economic results

Finally, the sensitivity analysis is also reinforced respect 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:

	<i>Potential of reducing illicit trade</i>							
	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 18: 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 19: 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.



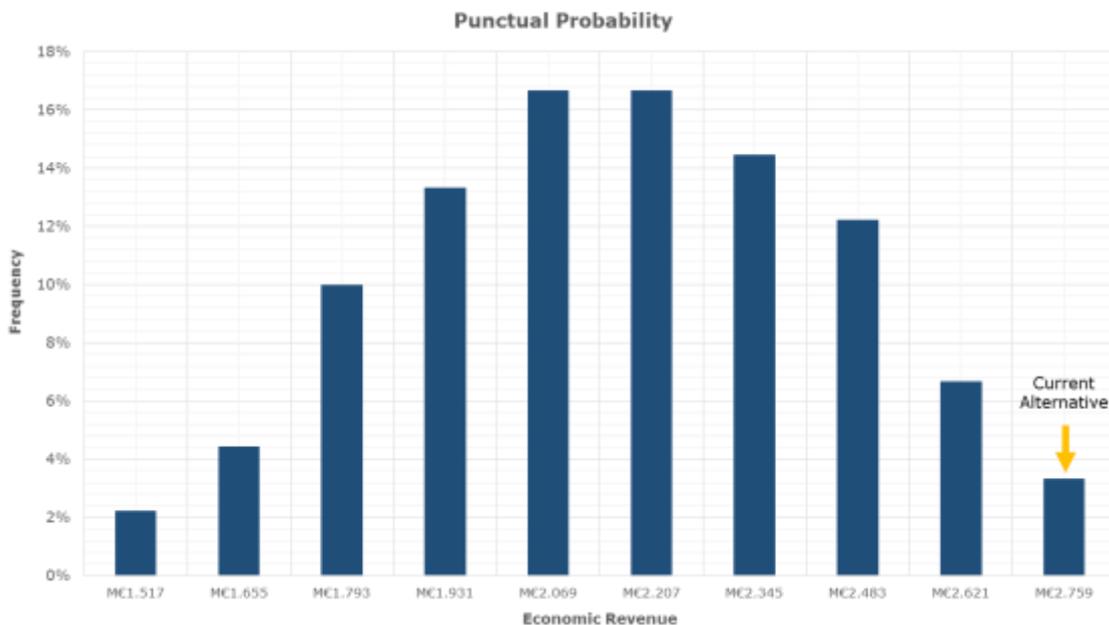


Figure 4: Probability density function of the economic revenue in base of the potential of reducing illicit trade

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 up to 1,517 million of Euros.

5.1.4. Statistical quantitative 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 provides a visual example.

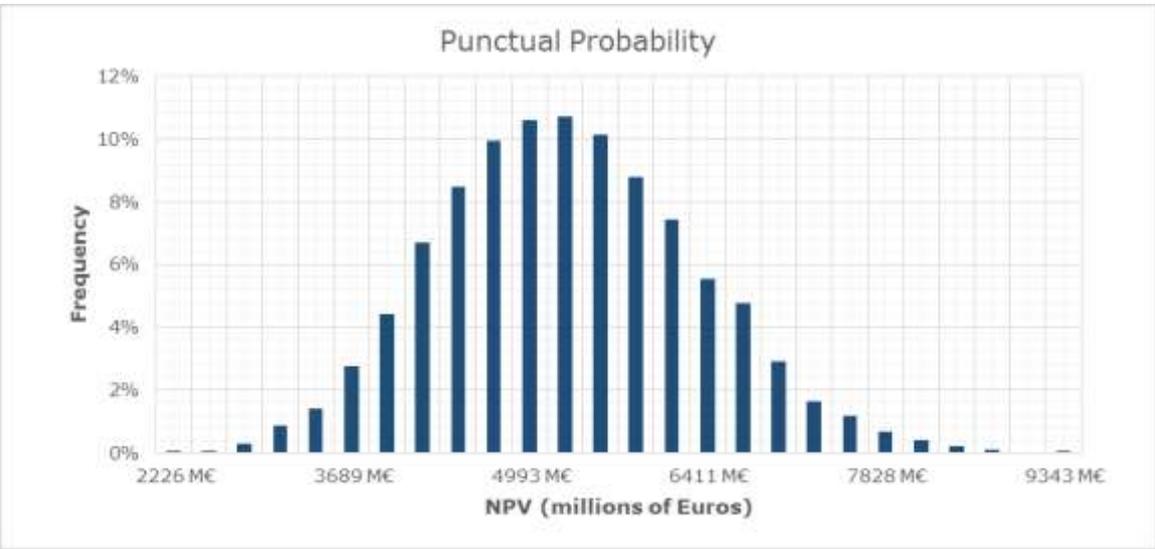


Figure 5: Probability density function of NPV

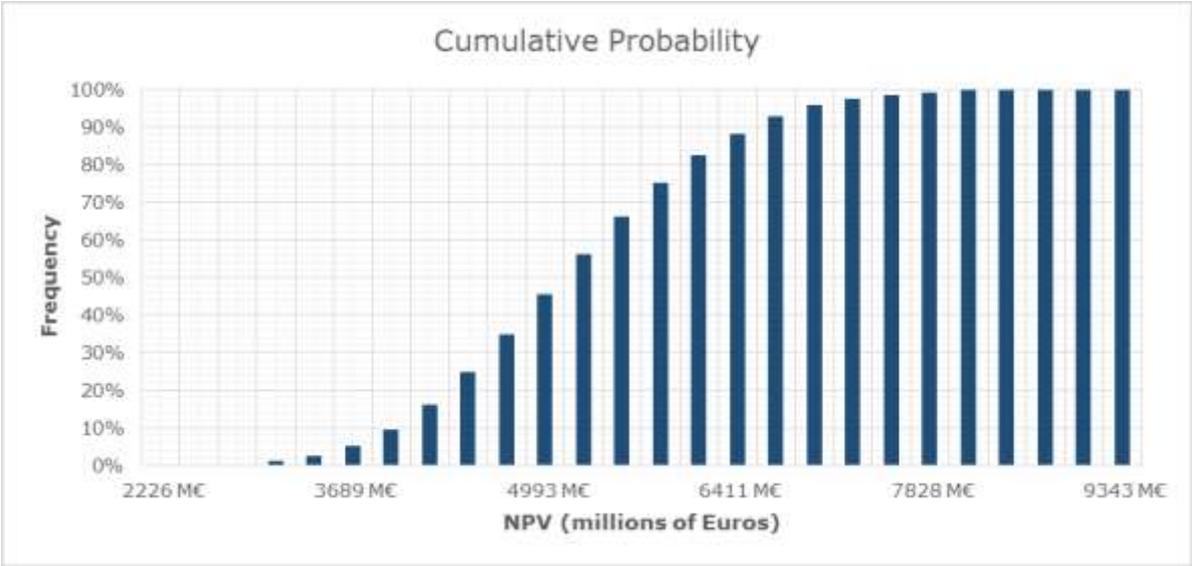


Figure 6: Cumulative probability of NPV

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 20: 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.

8. ANNEX B: DETAILED CALCULATION OF THE COSTS

In order to support the evaluation performed in Chapter 4 of 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 public 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).

8.1. 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.

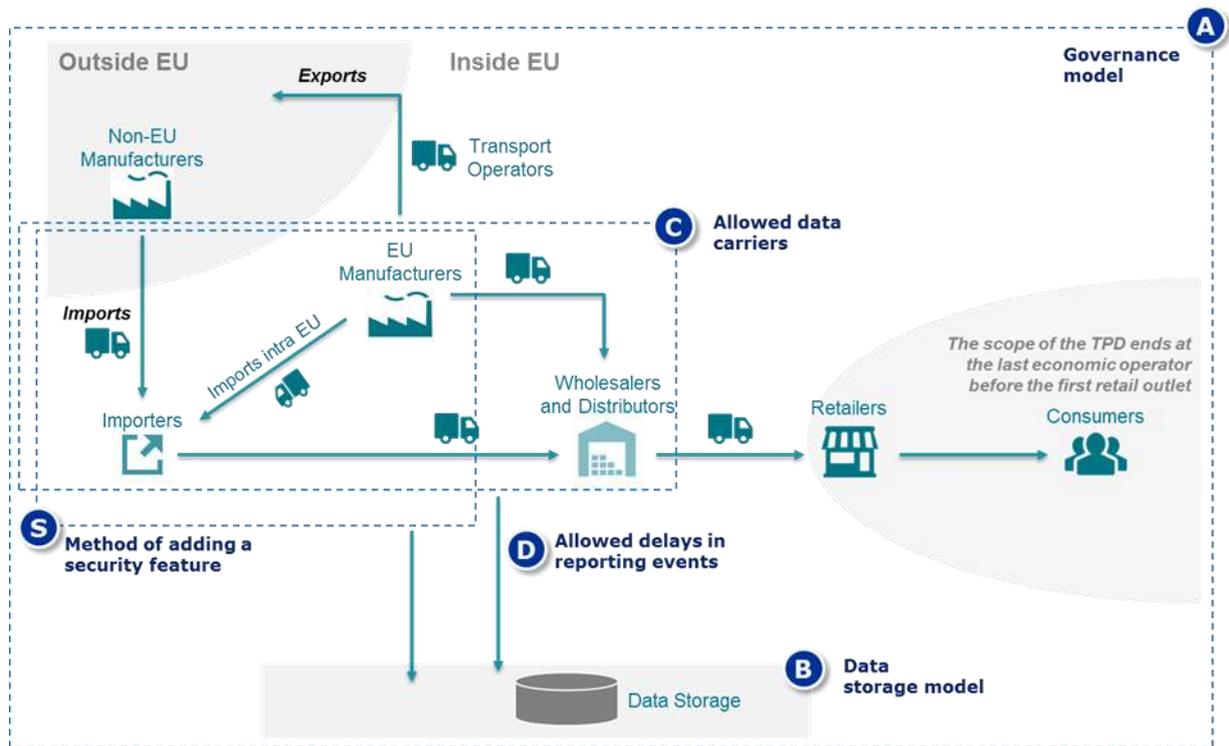
For option B (Data storage model), the aim of the data storage is to store all relevant data reported by the economic operators, assure its integrity, and make it accessible to the competent authorities for surveillance purposes. Identified costs are related with software, hardware, communications and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

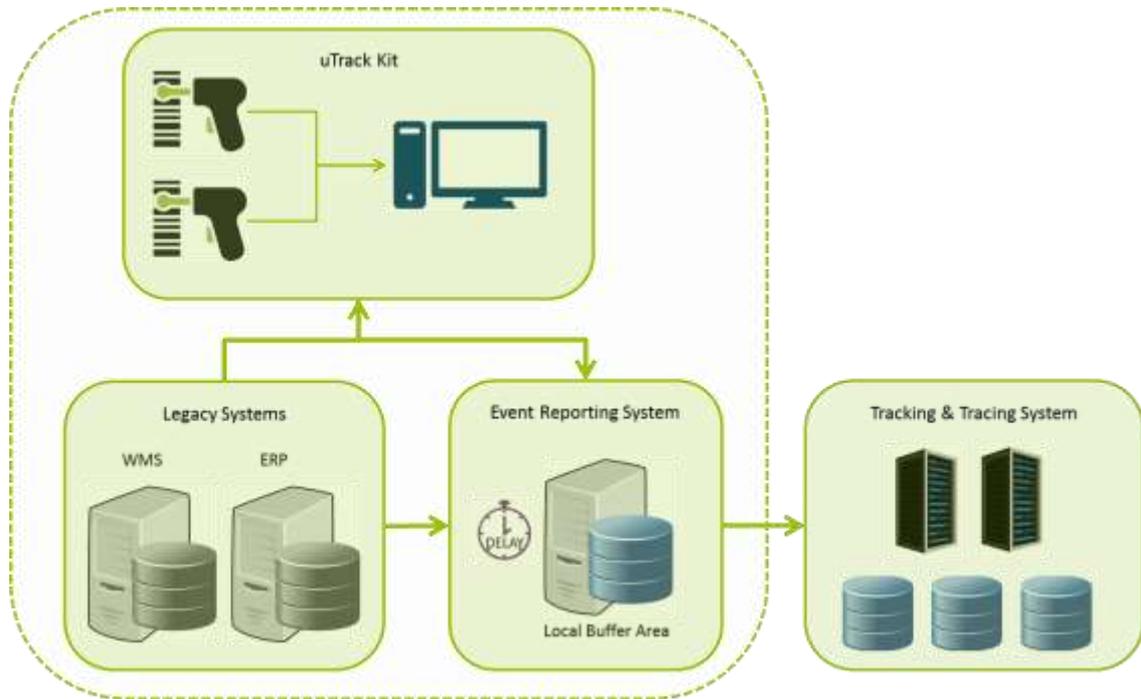
Financial Figures	Value	Source
Depreciation of all capital expenses	6 years	Feasibility Study (European Commission - Feasibility Study, 2015, p. 295)
Annual maintenance costs (HW or SW)	10% of CAPEX	Feasibility Study (European Commission - Feasibility Study, 2015, p. 300)

Commercial margin for the Independent Third Party	10%	Feasibility Study (European Commission - Feasibility Study, 2015, p. 301)
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uTrack kit description:

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

uTrack kit description	
Composition	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	<p>Shipment's reception of tobacco products in a warehouse</p> <ol style="list-style-type: none"> 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.



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 ²	Source
Mastercase distribution	25%	Team Operational experience
Pallet distribution	50%	Team Operational experience

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

Disaggregation

Figures	Value ³	Source
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² 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

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
<p>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)</p> <p>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)</p>	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.

8.1.1. Volumes

Annual Consumption

Figures	Value	Source
Cigarettes - Unit packets	24,395,800,000	Inception Impact Assessment (European Commission - TPD Inception Impact Assessment, 2016)

³ 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

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	
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 , Centre on Transational Crime (2015) (Centre on Transational Crime, 2015)	% of product price without taxes, Taxation and costumer union (European Comission - Taxation and Costumer Union, 2016)	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

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

- 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)

		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)

8.1.2. 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	LS Prod Lines	6,000€	13,000€	9,500€	Feasibility Study (European

Installation)					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
Master case 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)

8.1.3. 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 public 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.		

Policy Option	Cost	Stakeholder	Comments	Type of Cost	Comments
	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	Public Authorities	Physical presence of law enforcement agents	OPEX	
	Audit of the system and the activities of the 3 rd party	Public 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	Public 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

Policy Option	Cost	Stakeholder	Comments	Type of Cost	Comments
	Data Carrier: - Scanning	Wholesalers, Distributors, Service Vans and Mobile sales forces	Scanning activities for reporting events	CAPEX and OPEX	<ul style="list-style-type: none"> • 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	Public 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 licences and registration).

8.2. Governance model

8.2.1. 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.

8.2.2. 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	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	Printing/affixing done by an independent third party. Assumption: A profit component for the independent third party is estimated,	Printing/affixing done by manufacturers and importers. Assumption: • Printing the unique identifiers for unit packets (high speed).

	tracing system is uncertain.	(high speed). • Affixing (labelling) the unique identifiers for aggregation levels. Printing/affixing done by big distributors for re-aggregation levels.	added to the cost calculated in A1.	• 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:	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

		<ul style="list-style-type: none"> • 1 FTE can control 1 high speed production line. • 0.5 FTE can control 1 low/medium speed line. 		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 customs authorities).	Regular and random audits.	Regular and random audits.	Regular and random audits (higher frequency). Assumption: • 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).

8.2.3. Figures, volumes and unitary costs

The following tables present the unitary costs (those not presented in section 8.1.2.) 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

Public 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)

8.2.4. Results

8.2.4.1. 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
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CAPEX	- €	- €	- €
OPEX	- €	14,014,551 €	14,014,551 €
Annual depreciation	- €	- €	- €
Annualised total costs (OPEX + depreciation)	- €	14,014,551 €	14,014,551 €

8.2.4.2. 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	- €	- €	221,333 €

parties to remove, repair, check and/or replace the tamper-evident solutions			
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
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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 DISTRIBUTOR	Master case 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 DISTRIBUTOR	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 €	- €

8.2.4.3. Permanent control of the system

Public 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 €	- €	- €
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Public Authorities - TOTAL

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

8.2.4.4. Audits of the system

Public 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 €

Public 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 €

Summary

TOTAL	A1	A2	A3
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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 €

PUBLIC 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 €
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8.3. Data storage models

8.3.1. 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.

8.3.2. 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.

8.3.2.1. 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 information. It is based on the data model specification of the ISO/IEC 19987:2015 EPC Information services.	10,240	ISO/IEC 19987:2015 EPC Information services standard (ISO/IEC 19987:2015 EPCIS, 2016)
Percentage of reverse logistics events over the total events. <i>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.</i>	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	8	(European Commission -

<p>point of manufacture, up to the retailer.</p> <p><i>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.</i></p>		<p>Feasibility Study, 2015) (Directive 2014/40/EU of the European Parliament and of the Council, 2014)</p>
<p>Percentage of the original size after compression</p> <p><i>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.</i></p>	65%	<p>Compression benchmarks: (MongoDB, 2015) (MongoDB, 2015) (IBM, 2011) (Augeri & Bulutoglu, 2007)</p>
<p>Percentage of trade events at a carton level (only considered in the pessimistic storage sizing scenario)</p>	50%	Contractor's expertise.
<p>Percentage of trade events at a mastercase level (only considered in the pessimistic storage sizing scenario)</p>	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* level⁴. 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 such, although this scenario is pessimistic, is also embracing some realistic operational assumptions. This

⁴ 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.

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.

8.3.2.2. 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. <i>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.</i>	7	It is based on the main components identified in the System Architecture section (see section 5.3)

<p>Number of servers in the Federation Services solution.</p> <p><i>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.</i></p>	6	It is based on the main components identified in the definition of the B2 and B3 data storage models
<p>Years of data in the "hot" storage tier.</p> <p><i>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.</i></p>	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
<p>Number of data storage solutions at options B2 and B4.</p> <p><i>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.</i></p>	7	Tobacco EU market share (European Commission - Economic analysis of tobacco products, 2013)
<p>Number of data storage solutions at option B3.</p> <p><i>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</i></p>	19	Estimation of the market size per Member State based on the Inception Impact Assessment

<p><i>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.</i></p>		
<p>Operational support per data storage solution. (OPEX)</p> <p><i>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.</i></p>	5 FTE per year	Team Operational experience
<p>Implementation of the data repository. (CAPEX)</p> <p><i>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.</i></p>	6 FTE per one year	Team Operational experience
<p>Customisation of the EPCIS server software. (CAPEX)</p> <p><i>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.</i></p>	4 FTE per one year	Team Operational experience
<p>Implementation of basic surveillance services. It includes the following features: dashboard, query tool, notifications and reporting. (CAPEX)</p> <p><i>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</i></p>	6 FTE per one year	Team Operational experience.

<p><i>development. Work Package 3 will specify the technical requirements to establish this figure more accurately.</i></p>		
<p>Implementation of the data management activities. (CAPEX)</p> <p><i>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 and database implementation. Work Package 3 will specify the technical requirements to establish this figure more accurately.</i></p>	<p>6 FTE per one year</p>	<p>Team Operational experience</p>
<p>Implementation of the discovery service. (CAPEX)</p> <p><i>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.</i></p>	<p>6 FTE per one year</p>	<p>Team Operational experience.</p>
<p>Implementation of the synchronisation process. (CAPEX)</p> <p><i>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.</i></p>	<p>6 FTE per one year</p>	<p>Team Operational experience</p>
<p>Implementation of the cross-cutting services. (CAPEX)</p> <p><i>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.</i></p>	<p>4 FTE per one year</p>	<p>Team Operational experience</p>

Software maintenance support (i.e. corrective and evolutionary). (OPEX)	3 FTE per year	Team Operational experience
<i>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.</i>		

8.3.2.3. 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

8.3.3. 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)

8.3.4. Results

8.3.4.1. 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 the 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

8.3.4.2. 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 €
Customization 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 €

8.3.4.3. 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 €

8.3.5. 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 €

8.4. Allowed data carriers

8.4.1. 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 it has been contemplated the same type activities in the distribution chain for all the tobacco products (including cigars, RYO, pipe tobacco and smokeless tobacco).

8.4.2. 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.

8.4.2.1. 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%

8.4.2.2. 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 consider 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	100% Big distributors and	50% Big distributors and

(Nomisma, 2012). (Germany, Spain, Portugal, Netherlands, Italy, Belgium, Austria, Czech Republic, Malta, Luxembourg)	wholesalers	wholesalers 25% Vending Machines Service 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% Master Case
Level 2 Distributor	75% Pallet 25% Master Case	75% Master Case 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

8.4.3. Figures, volumes and unitary costs

Most of the unitary costs used in this analysis were specified in the introductory section 8.1 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 Research Centre on Transnational 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 (million 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

8.4.4. 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 Pprinter & 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 master case - High speed production lines	- €	- €	- 104,328 €	- 104,328 €	- 208,656 €
Cost of printing master case – 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 organizations - 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 organizations - 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.

8.4.5. 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 €

8.5. Allowed delays in reporting events

8.5.1. 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 in section 3.4, 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 to 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.

8.5.2. 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).

8.5.2.1. 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 in section 3.4, 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%	-	-

8.5.2.2. 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 regards 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%	-	-

8.5.3. 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	<ul style="list-style-type: none"> 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 	1,500€	3,068€	2,284€	(Dell inc., 2016) (Ebuyer (UK) Limited, 2016)

	Install <ul style="list-style-type: none"> • Basic Deployment Manufacturer Service 				
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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	Service	Medium	1	72	Implementation of the data inbound

Endpoint					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€	

8.5.4. 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€

8.5.5. 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€
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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€
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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€
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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 €

8.6. Method of adding a security feature

8.6.1. 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 medium 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	5	4,848,802,787	18.34%	Team Operational

stamps that could be required to update to be compliant with the TPD under options S1 and S3				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 State⁵ 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	

⁵ Average consumption of a Member State = Total consumption of the 28 MS / 28

	MS using affixed tax stamps	MS not using tax stamps
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

8.6.2. 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	PRINTED (S2)

packets	
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Security features

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

Methods of applying per tobacco product

	S1	S2	S3
Affixed - Dry label	<ul style="list-style-type: none"> • Cigarette packs = 100% • RYO = 100% • Cigars = 70% 		<ul style="list-style-type: none"> • Cigarette packs = 100% • RYO = 100% • Cigars = 70%
Affixed - Self-adhesive label	<ul style="list-style-type: none"> • Cigars = 30% • Pipe tobacco = 100% • Smokeless chewing tobacco = 100% • Smokeless tobacco snus = 100% 		<ul style="list-style-type: none"> • 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		<p>Printing or integrating through a different method to all types of tobacco products = 100%</p>	

8.6.3. 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)

8.6.4. 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 €

8.6.5. 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
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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 €

Annex C: Detailed Calculation of the Benefits

9.1. 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%

Table 21: Consumption breakdown – Detailed calculation

The report still 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 Research Centre on Transnational 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

Table 22: 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 in 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 (%)

	$(K) = (H) \cdot 10\%$	$(L) = (I) \cdot 10\%$	$(M) = (J) \cdot 30\%$	$(N) = (K) + (L) + (M)$	$(O) = (N) / (B)$	$(P) = (N) / (C)$
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 23: 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.

The estimation of price elasticity and cost of illicit tobacco products was detailed in chapter 5. Based on these conclusions the price elasticity per country in Europe has been estimated based on their GDP per capita in Purchasing Power Standards (PPS), where the average of EU28 is set to equal 100 (Eurostat, 2016). 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:

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

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 an increment of 100% in price.

$$\begin{aligned} \Delta Q\% &= \frac{Q_1 - Q_0}{Q_0} = \frac{e^{b_0 + b_1 \cdot \ln(P_1) + f} - e^{b_0 + b_1 \cdot \ln(P_0) + f}}{e^{b_0 + b_1 \cdot \ln(P_0) + f}} = e^{b_1 \cdot (\ln(P_1) - \ln(P_0))} - 1 \\ \Delta Q\% &= e^{b_1 \cdot \ln \frac{P_1}{P_0}} - 1 = e^{\text{PriceElasticityCoefficient} \cdot \ln 2} - 1 \end{aligned}$$

Three ranges of price elasticity coefficients have 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 24: Price elasticity

	GDP per capita in PPS (EU28 = 100) (Eurostat, 2016)	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

Table 25: 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.

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

The following table represent 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 (€) (Transcrime, Joint	Average VAT (%) (European Commission - Taxation and Consumer	Excise duties as % of the price (European Commission - Excise duty tables,	EO's revenue as % of the price	Impact on VAT (M€)	Impact on excise tax (M€)	Impact on EO's revenue tax (M€)
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	Research Centre on Transnational Crime, 2015)	Union, 2016)	2016)				
	(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

Table 26: 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.

9.3. 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 27: Different percentage reduction in tobacco consumption

As it 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:

$$\begin{aligned}
 & \text{Decrease in healthcare expenditure (M€)} \\
 & \quad = \text{Coefficient}_{\text{Healthcare}} \cdot \% \text{Reduction in tobacco consumption} \\
 & \text{Increased productivity (M€)} \\
 & \quad = \text{Coefficient}_{\text{Productivity}} \cdot \% \text{Reduction in tobacco consumption} \\
 & \quad \text{Coefficient}_{\text{Healthcare}} = 25,300 \text{ (D')} \\
 & \quad \text{Coefficient}_{\text{Productivity}} = 8,300 \text{ (E')}
 \end{aligned}$$

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

Table 28: Estimated socio-economic benefits

9.4. 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 people)	Current smoking rate of tobacco (%) (Transcrime, Joint Reaseach Centre on Transational Crime, 2015)	Number of people who will reduce or quit 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
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Table 29: 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
<i>Missing values for Croatia and Cyprus</i>			

Table 30: Assessment for the calculation of the social and environmental benefits (II)

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ANNEX 7 – COMMENTARY ON THE COST-BENEFIT ANALYSIS

The cost-benefit analysis carried out by the Commission's contractor, Everis, presented in Annex 6 is further supplemented with the below notes relating to the estimations of benefits and costs. The notes focus on the key considerations for the overall outcome of the analysis, i.e. the magnitude of benefits and costs.

Everis' analysis has also been considered in view of (a) the earlier cost-benefit analysis carried out for the purpose of the Feasibility Study and (b) the comments received during the stakeholder consultation process.

A.7.1 Comments on the reference level of social and economic benefits

A.7.1.1 Potential of the systems of traceability and security features to reduce illicit trade in tobacco products

Traceability and security feature systems are generally seen as an effective means to combat the illicit trade in tobacco products. Both measures have already been developed and used by industry in recent years, but as explained no truly comprehensive system has yet been put in place at the regional (or EU) scale. An effective traceability system could be expected to lead to a non-negligible reduction in illicit trade, up to 30%.¹ A security feature should further reinforce the safety of the legal supply chain by helping consumers and law enforcement agencies to identify illicit products. The combined effect of both the traceability and security feature systems can be illustrated with the example of the California Tobacco Licensing and Control Act. It is claimed that the introduction there of a bar code tax stamp, i.e. a feature that combines characteristics of a state-of-the-art tax stamp with a traceability element, along with licensing measures and enforcement, led to a drop from 14 percent to 2 percent in the number of illicit cigarette seizures over a five-year period. This can serve as a proxy for an expected similar decrease in the size of the illicit market in the EU.²

Against the foregoing, it is conservatively assumed that the initiative has the potential to reduce illicit trade in the order of 30% for contraband, 10% for counterfeit, and 10% for illicit whites.³ Lower percentages assumed with respect to counterfeit and illicit white products are due to the fact that these types of illicit products usually originate outside of legal manufacturing facilities and hence are more difficult to fight with the traceability system, i.e. the tool primarily aimed at discovering product diversions within the legal supply chain, e.g. fictitious exports⁴. This being said, contrary to the claims of certain stakeholders, both the traceability system (by providing powerful analytical tools) and

¹ The TPD Impact Assessment, page 108.

² California State Board of Equalisation, News Release of 27 May 2010.

<http://www.boe.ca.gov/news/2010/62-10-H.pdf>

³ The main categories of illicit products are: contraband (i.e. products which have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination), counterfeit (i.e. brand protected products which have been falsified without consent of the brand owner and are not respecting the legal requirements in the jurisdiction of destination) and illicit/“cheap” whites (i.e. products produced (often legitimately) in their country of origin at very low cost, destined to be smuggled into other jurisdictions and not respecting requirements in the jurisdiction of the destination. Illicit products may be also sourced from illicit manufacturing within a given jurisdiction.

⁴ See the example of a case of a contraband network disbanded by Italian and German law enforcement authorities with OLAF support in November 2014 https://ec.europa.eu/anti-fraud/media-corner/press-releases/olaf-supports-italian-authorities-dismantling-major-network-euro_en

security feature system (by improving product authentication) are highly likely to assist the enforcement authorities in efficiently fighting against all types of illicit products, including counterfeit products and illicit whites. Furthermore, the close monitoring of the legal supply chain can provide for very good general indications with respect to illicit trade activity. In particular, given the short-term rigidity of the demand for tobacco products, any abrupt fluctuations in the legal flows of tobacco products will allow both outflows and inflows of illicit products from/to the legal supply chain to be identified (see case studies set out in section 1.2 of the main report).

A.7.1.2 Quantitative impacts of the optimal system on the sales of tobacco

Given the present size of the illicit segment in the total tobacco products market (see Table 1 in the main report), the initiative could generate a reduction in illicit trade equal to 2.45% of the total tobacco products market (or 21.72% of the illicit market), which translates into 674 million cigarette packs per year⁵. As to individual Member States, the impacts are modelled to reflect the different size and composition of illicit tobacco sales assumed for their respective territories.⁶

The reduction in illicit trade is expected to have two effects: (a) an increase in the legal sales of tobacco products along with the related increase in the amount of collected taxes, and (b) a simultaneous decrease in overall tobacco consumption leading to a positive impact on health and important gains for the economy in terms of healthcare savings and productivity improvements.

The Implementation Study assumes that the full potential of benefits will be gradually achieved over six years from the launch of the system, i.e. over the period 2019 to 2024. It is also worth noting that the benefits are strictly proportionate to the initiative's impact in terms of the reduction of illicit trade.

A.7.1.3 Economic benefits expected from the optimal system

On the basis of the existing estimates of price elasticity of demand for tobacco⁷ adapted to the log-linear demand function⁸ and price differences between licit and illicit supplies⁹, it is assumed that the initiative may result in an increase of legal sales by 510 million cigarette packs per year and a decrease of total consumption by 164 million cigarette packs per year. The expected increase in legal sales may provide EUR 2 billion per year in collected taxes

⁵ The benefit analysis is based on the statistics of illicit trade in the main segment of the tobacco products market, i.e. cigarettes, for which market estimates are readily available. This is a conservative approach, which likely leads to underestimation of the total benefits brought about with the present initiative.

⁶ See Table 3 in the Impact Assessment and section 9.1 of the Implementation Study in Annex 6.

⁷ Estimates for high-income countries are clustered around -0.4 , see: U.S. National Cancer Institute and World Health Organization. *The Economics of Tobacco and Tobacco Control*. National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016.

⁸ The log-linear demand function is considered to better reflect the nature of the demand switch from illicit to licit tobacco. The function assumes that the demand curve steepens up with further incremental increases in prices. This assumption is more realistic in view of the demand characteristics (i.e. the presence of the consumers with varied degrees of addiction among current smokers and the dissuasive effects of prices on new initiations). Under the assumed demand function, the elasticity of -0.4 (most often reported in the studies, see footnote 7 above) translates into the corresponding decrease in the quantities demanded by around 24%.

⁹ An average price ratio of licit to illicit cigarettes is estimated at 2 to 1 following the research studies summarised in: Joossens L, Merriman D, Ross H, Raw M. *How eliminating the global illicit cigarette trade would increase tax revenue and save lives*. Paris: International Union Against Tuberculosis and Lung Disease; 2009.

(i.e. VAT and excise duties) and EUR 59 million per year in additional profits for the economic operators involved in the value chain of tobacco products¹⁰.

A.7.1.4 Social benefits expected from the optimal system

The present analysis closely follows the TPD Impact Assessment¹¹ and assumes that the proposed system should be expected to decrease in particular the number of young people who start smoking (it is recalled that 90% of smokers start before the age of 25 years¹²). In addition, it is expected that some of the existing smokers will quit smoking in response to the higher prices of legal tobacco (as compared to the illicit products). Similar to the TPD Impact Assessment, both non-initiation and cessation are assumed to be captured by the projections of tobacco consumption.

The main positive impact of reduced tobacco consumption is significant improvement in public health. While the improvements with respect to certain tobacco related acute diseases (e.g. respiratory illnesses) are expected to be seen within relatively short time periods, the effect on some other diseases (e.g. cancers) may take several decades to fully materialise. The TPD Impact Assessment assumed that, on average, smokers die 14 years earlier as a result of their tobacco consumption than people who never-smoked.

The TPD Impact Assessment considered the value attributed to each life year gained, not the value of a lost life itself. The value of one life year (VOLY) was based on the surveys and observations made in the research project ExternE, which suggested the median VOLY of EUR 52 thousand irrespective of the age or country of residence of the victim. The same value has been retained for the purpose of the present analysis.

According to the TPD Impact Assessment, apart from the improvement in public health (i.e. decreased mortality and longer healthy life years), the reduced tobacco consumption will lower healthcare costs and improve social productivity thanks to fewer cases of absenteeism and premature retirements. The same approach (as well as the respective monetary valuations of savings in healthcare expenditure and gains in social productivity) has been adopted in the present analysis.

For the purposes of this analysis, the consumption projections (i.e. the expected decrease of 164 million cigarette packs per year) were combined with the monetary values assumed under the TPD Impact Assessment. On this basis, it is expected that the initiative may generate savings in healthcare expenditure in the range of EUR 165 million per year and a gain of EUR 54 million per year in social productivity (i.e. reduction in smoking induced early retirements and work absenteeism). It is also expected that the initiative may lead to an increase of the discounted monetary value of saved lives by EUR 1.5 billion.¹³

A.7.1.5 Criticism by industry stakeholders

The above approach to the calculation of social benefits was criticised by certain stakeholders who claimed that consumers are unaware that they are buying illicit tobacco

¹⁰ The profits were established on the basis of (a) the expected increase of EUR 525 million per year in terms of additional revenues for the economic operators and (b) the profit margin assumed for each type of the economic operator (i.e. manufacturers, distributors/wholesalers and retailers) under the TPD Impact Assessment, Annex 5, page 6.

¹¹ TPD Impact Assessment,.

¹² See: *Attitudes of Europeans towards tobacco and electronic cigarettes*, Eurobarometer Special Surveys 458. <http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146>

¹³ The non-discounted value of saved lives equals to EUR 3.1 billion. This value was discounted with a discount rate of 3% over a period of 25 years in line with the most likely scenario assumed under the TPD Impact Assessment, Annex 5, pages 30-31.

products and already pay the regular price, and hence the measures are not likely to lead to any reduction in consumption. However, if this claim was correct, it would mean that the illicit buyers source their purchases from the legal establishments (only then they can be "unaware"). Such a supposition would instead reinforce the need for the traceability system, which is aimed at controlling the legal supply chain and will also provide valuable insights into the quantities sold at individual retail outlets (on the basis of the quantities dispatched by distributors). In this scenario, the efficiency of the measure would surely surpass the assumed reduction rates in illicit trade and would result in significantly higher economic benefits.

Another line of criticism concerning the analysis of the social benefits was based on the recourse to other cheap tobacco products. However, the existing statistics on the sales of cigarettes and fine-cut tobacco (the closest substitute) suggest strong limitations as to this type of substitution. For example, the release for consumption data indicates that in the period 2011-2015 the quantities of fine-cut tobacco flattened out, which was in sharp contrast to the continuous downward trend observed as to the release for consumption of relatively more expansive cigarettes.¹⁴

A.7.2 Comments on the cost estimates

A.7.2.1 Overall costs

The estimates presented in Annex 6 have been compared with the estimates provided during the stakeholder consultations process. Such a comparison is naturally susceptible to a number of underlying assumptions about the precise design of the system in question. In turn, the design of the system depends on the selection of options considered under the present IA. Nonetheless, the comparison has been carried out in order to assess, in broad terms, the extent to which cost estimates may vary.

It must be stressed that most of stakeholders had difficulties providing any accurate figures on the costs of establishing the key building blocks of the future system, i.e. marking packages with a unique identifier. This is understandable in view of the lack of direct experience with past investments of similar type.

However, two major manufacturers referred in general terms to their past investments made in designing and implementing their own systems, which included the generation, application and verification of unique identifiers. The claimed investments were higher than the estimates presented under option 1a/1. If the annualised costs are compared in terms of costs per unit packet marked, the estimates presented by those two manufacturers were higher up to the factor of 2.5 as compared to the estimates presented under option 1a/1.

In parallel, another major manufacturer and a large solution provider reported estimates that were equal to and even 50% lower than the estimates presented under option 1a/1, respectively.

Against the foregoing, it has been concluded that the present IA's estimates fall within the range of plausible values. In addition, as to the upper range of the estimates, it can be assumed that the technological progress, including the experience gained by the industry in building their own systems, should lead to considerable savings in future deployments.

¹⁴See:

http://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxation/excise_duties/tobacco_products/tobacco_products_releases-consumption.pdf

A.7.2.2 Costs of third party operated solution

During the consultations, several economic operators and their associations pointed at a higher cost of the third party operated system arguing that any new system would necessarily incur higher costs compared to an established system. By the latter, the industry's own systems were referred to. Other respondents also argued that printing a data carrier directly on a package is much more efficient than labelling a package with a data carrier, while the latter was implicitly assumed to be the technology of choice of independent service providers.

These comments seem to be based on two false assumptions that: (a) there is no possibility for the sale or lease of existing assets compatible with a new system from the industry to independent service providers (b) independent service providers will necessarily offer a less efficient technology.

ANNEX 8 – Who is affected, in what ways, and to what extent?

The *General public*, together with the public authorities, is the group most affected by the issues at stake. In the absence of effective tracking and tracing and security features, tobacco products not compliant with the TPD and other EU and national legislative provisions would be made available in considerable quantities to the general public. This means that consumers and citizens would not benefit from the provisions included in the TPD, especially with regard to health warnings and ingredients regulation. In addition, the fact that illegal products are substantially cheaper affects smoking initiation, especially among young people, and prevalence.¹ The measures foreseen in this Impact Assessment are thus expected to lead to reduced tobacco consumption, improved health among EU citizens and increased healthy life-years.

Governments/Society are also affected by the issues at stake, both in terms of the level of health protection, costs associated with treating smoking related diseases,² as well as loss of budgetary revenues resulting from unpaid taxes on these products. In relation to the first consequence, as previously stated, the presence of illicit products on the market contributes to increasing smoking initiation and prevalence, meaning increased costs relating to the treatment of smoking-related disease, lower healthy life years and reduced productivity. As to the second consequence, a recent study estimated the amount of taxes that EU tax administrations lose to illicit trade at about €11.1 billion a year³. It has been estimated that the elimination of illicit trade would increase tax revenues in the range of €6.1 billion to €7.2 billion a year.⁴ In addition it should be underlined that smuggling of tobacco products provides non-negligible profits to criminal organisations, which represent serious threats in terms of public security.⁵ Effective track and trace as well as security feature systems is estimated to improve public health overall (an aim in itself) and reduce significantly health care expenditure.

Manufacturers and importers, as well as economic operators involved in the supply chain of tobacco products are also affected by the lack of a tracking and tracing system. Indeed the fact that illicit products are available to consumers reduces the amount of legal products sold, resulting in economic losses for manufacturers and importers. Reducing the illicit supply is expected to direct a part of the demand towards the legal supply chain.⁶

¹ In the Impact Assessment accompanying the Proposal for a Tobacco Products Directive, it is confirmed that thanks to the adoption of a tracking and tracing system, part of the demand previously met by illicit products is expected not to be substituted by legal products, i.e. would result in reduced consumption, see page 110 of the Impact Assessment. See Annex 6.

² According to the estimation contained in the Impact Assessment accompanying the Proposal for a Tobacco Products Directive, healthcare expenditure on treating smoking attributable diseases is estimated to be around 25 billion EUR, which corresponds to 2.89% of total healthcare spending in the EU27 and 0.22% of GDP, see page 20 of the Impact Assessment.

³ Inception Impact Assessment on the implementing and delegated acts under 15(11), 15(12) and 16(2) of Directive 2014/40/EU, page 2.

⁴ Study on the measuring and reducing of administrative costs for economic operators and tax authorities and obtaining in parallel a higher level of compliance and security in imposing excise duties on tobacco products, see:

http://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxation/excise_duties/tobacco_products/studies_reports/ramboll-tobacco-study.pdf

⁵ Inception Impact Assessment on the implementing and delegated acts under 15(11), 15(12) and 16(2) of Directive 2014/40/EU, page 3-4.

⁶ Impact Assessment accompanying the Proposal for a Tobacco Products Directive, p. 110. See Annex 6.

As outlined in the Feasibility Study⁷ the key actors of the tobacco supply are:

- *Manufacturer*:⁸ any natural or legal person that acquires raw materials and processes them in order to produce a tobacco product, which is then sold to wholesalers and retailers (and importers in the case of manufacturers outside the EU);
- *Importer*: owner of, or a person having the right of disposal over, tobacco products that have been brought into the territory of the Union;⁹
- *Wholesaler/distributors*: any natural or legal person that acquires tobacco products from manufacturers or importers and either distributes to a distributor or sells them to an agent / another wholesaler;

As represented in Figure 1, tobacco products may be produced inside or outside the territory of the Union. In the latter case these products enter in the EU territory through an "importer"¹⁰. Once a unit packet is manufactured (e.g. a packet containing 20 cigarettes) it is then placed into a second layer, or even third layer of packaging (e.g. 10 cigarette packets are placed into a carton, and 50 cartons into a master case).

In a general scenario, after the production (or importation) tobacco products are transported to the wholesalers and distributors facilities¹¹. At this stage of the supply chain products might be repackaged on the basis of the elements that should be despatched to the retailer (e.g. some pallets could be opened and mastercases contained in it would be placed into a new pallet).



Figure 1: *Tobacco supply chain*

It should be borne in mind that while the tobacco manufacturers exclusively manufacture and ship tobacco products, other operators involved in the supply chain (such as wholesalers and distributors) may be dealing with other goods besides tobacco.

⁷ Feasibility Study, pages 58-59.

⁸ This reflects the definition of "manufacturer" provided by the TPD, which refers to any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark (Article 2(37) TPD).

⁹ According to the TPD the definition of "import of tobacco or related products" refers to the entry into the territory of the Union of such products (Article 2(38) TPD).

¹⁰ In some cases products could be imported by manufactures or wholesalers.

¹¹ As highlighted in the Feasibility Study, the number of possible combinations of supply flows applicable to the tobacco business is diverse, especially when commercial exceptions such as damaged, returned and repackaging of goods occur, p. 58.

Finally, *solution providers* are also affected by the issues at stake. It is likely that they will play a role in providing supply chain operators with the technical equipment necessary to carry out the operations foreseen under article 15 and 16 of the TPD. Implementation of the systems provided for under these articles is therefore likely to have a positive effect on employment opportunities for this stakeholder category.

The table below illustrates the accountability of the various actors at relevant stages of the systems under the **preferred policy options**:

Task	Accountable actor
Generation of Unique Identifiers	Independent third party
Application of Unique Identifiers on unit packets/aggregated packaging levels	Economic operators
Verification of Unique Identifiers on unit packets/aggregated packaging levels	Economic operators; Independent third party
Aggregation	Economic operators
Reporting and transmission of data on product movements	Economic operators
Reporting and transmission of transactional data	Economic operators
Approval of data storage contract and suitability of independent third parties responsible for primary data storage	European Commission
Data storage	Independent third party
Approval of external auditor responsible for monitoring third party data storage, and proposed and paid by tobacco manufacturers/importers	European Commission
Application of compliant security features on unit packets	Economic operators (manufacturers and importers)
Surveillance and enforcement	Competent authorities

ANNEX 9 – REGULATORY SCRUTINY BOARD

A first version of this Impact Assessment was submitted to the Regulatory Scrutiny Board on 22 March 2017. On 27 April 2017, the Board met with DG SANTE.

Following this meeting, the Regulatory Scrutiny Board acknowledged the extensive work to explore different options and assess their likely impact set out in the draft Impact Assessment. It delivered a positive opinion and recommended to further improve the report by:

- (1) Clarifying the reasons for discarding the option of a centralised database.
- (2) Strengthening the assessments of costs and, especially, health benefits.
- (3) Clarifying how the proposed EU system would ensure effective global tracking and tracing of tobacco products.
- (4) Better highlighting how security features help make the proposed system innovative and robust to future technological developments.

Based on these comments the draft was revised and the recommended clarifications added, notably in the following sections:

Section 4.3.1: This section has been amended to further clarify the reasons for non-inclusion of a centralised storage system amongst the policy options relating to data storage.

Section 5, Section 6, Annex 7: These sections have been further reinforced with additional key information relating to the assessment of costs and health benefits of the measures.

Section 1.2, Section 2.2, Section 2.3 and Section 3.2: These sections have been revised to better explain and reflect this important aspect of global interoperability of the EU's traceability system. Notably, 'international interoperability' has been added in Section 3.2 as a specific objective of the measures to be adopted.

Section 2.1 (issue 3) and Section 4.5: These sections have been reinforced in order to highlight the importance of allowing sufficient space for innovation in the area of security features, which contributes to ensuring that they remain capable of providing high levels of protection against fraud.

ANNEX 10 – Summary of third country implementation of traceability systems

A limited number of FCTC Parties (Brazil, Turkey and Kenya) have already implemented specific marking systems for tobacco products.

Brazil

- (As taken from the website of the FCTC¹) In 2007 Brazil introduced a control and monitoring system and required a digital tax-stamp system capable of identifying each individual pack. The digital stamp uses invisible ink and features a unique, covert code with data for each pack. These codes contain product data for each cigarette pack, which is uploaded to a Data Manager Server under the control of the Ministry of Finance. The Brazilian control and monitoring system was updated in 2011. Federal law requires that every pack of cigarettes produced in Brazil for export has to be marked with a unique identification code at the production lines to determine the origin of the products and to control their movement. The marking regime applied to cigarettes for export is a visible two-dimensional matrix code (instead of an invisible code for the domestic products) on the packs and the cartons. At the end of the numeric code, the letters BR will be added, indicating that the cigarettes were produced in Brazil. Through a link with the Internet, enforcement officials will have access to information (such as date and place of manufacture and country of destination) to trace the pack by entering its numeric code.

The Brazilian system applies only to domestically manufactured products.²

One single third party solution provider is in charge of providing the above-mentioned services in Brazil.³

Turkey

- (As taken from Framework Convention Alliance's fact sheet, *'The use of technology to combat the illicit trade'*⁴) Turkey also introduced a similar digital tax stamps system in 2007. This kind of stamp uses invisible ink and features a unique, covert code with data for each pack (containing 20 cigarettes). The tax stamps let you verify whether products are authentic or counterfeit, and the stamps can be encrypted with extensive

¹ <http://www.who.int/fctc/protocol/faq/en/index3.html>

² Euromonitor International (19 December 2012), 'Fighting Illicit Trade in Tobacco with Technology: Does it Work?'

<http://blog.euromonitor.com/2012/12/fighting-illicit-trade-in-tobacco-with-technology-does-it-work.html>

³ http://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20120524_mi_en.pdf

⁴ http://www.fctc.org/images/stories/INB-2/INB-2_Factsheet_Use_of_Technology2.pdf

information that is uploaded to a Central Data System. Scanning of the tax stamps allows immediate detection of counterfeit cigarettes.

- The system was aimed at both tobacco products and alcoholic beverages. The system applies to cigarettes made in Turkey and to legally imported cigarettes. That is its chief difference with the similar tax-stamp system in Brazil, a country that does not import cigarettes. In Turkey, the tax stamps are applied on cigarette packs in foreign and domestic manufacturing sites. For domestically made cigarettes, codes on the tax stamps are activated at the manufacturing site, and for imported cigarettes , they are activated in one of the three customs ports.

Kenya

- 2014: Installation of real time tracking and tracing system tax stamps.⁵
- (Based on 'Tracking and tracing tobacco products in Kenya', by Hana Ross, 2017⁶) In April 2013 Kenya set up the excisable goods management system (EGMS) for tobacco and alcohol products, which allows for production counting, T&T, stock control, tax forecasting, forecasting and processing of tax stamps, and collecting other business intelligence. The EGMS relies on electronic digital stamps that serve as proof that both excise tax and VAT have been paid. The new stamps are affixed on each pack in such a manner that removal would make them unusable. They have overt security features for the general public (e.g., holograms, color shifting), semi-covert security features for the supply chain actors, covert security features (e.g., fluorescent fibers, security ink) for the tax authority, and forensic security features (e.g. taggants) to support prosecution.
- Cigarette manufacturers are required to affix photosensitive readers on production lines to transmit real-time production data to Kenya Revenue Authority (KRA) servers. Cigarette importers purchase electronic digital stamps in Kenya and send them to their facilities abroad where they are affixed on each pack destined for Kenya. All domestic producers and importers must activate an excise stamp online. Tobacco products designated for export are not marked, because these products are already subject to a tight electronic cargo monitoring system introduced in 2010.
- The T&T system requires high-speed broadband Internet and a reliable telecommunication network. KRA officials are equipped with handheld devices that can swipe a hidden photo-magnetic line embedded in the stamp and transmit real-time data such as the date of issue, the producer's name, the product category, and the brand to the central server. These devices can also be used offline for authentication of the stamp and for tracking and tracing of the stamp. This allows for quick verification of the legality of a product at any point in distribution. Cigarette distributors and retailers have a device that allows for verification of all tobacco products before accepting them into their outlets. All major supermarkets participate in the system and are

⁵ <http://apps.who.int/ctc/implementation/database/article/article-15/indicators/5700/reports>

⁶ Ross, H – (2017). 'Tracking and tracing tobacco products in Kenya'
<http://www.sciencedirect.com/science/article/pii/S0091743517301457>

connected to KRA servers. In 2016, KRA released an app known as the KRA Stamp Checker, which allows the public to verify the genuineness of both cigarettes and alcohol using mobile phones.

- The rollout of the T&T system took approximately 11 months and was finalized in March 2014. The system is self-funding, since the companies pay for the readers installed in their facilities and are allowed to expense this cost, thus reducing their tax liability.

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