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IMPACT ASSESSMENT

Accompanying the document

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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

{C(2017) 8429 final} - {C(2017) 8435 final} - {SWD(2017) 456 final} -
{SEC(2017) 531 final}

List of acronyms

Capital expenditure	CAPEX
Enterprise resource planning	ERP
European Union	EU
Operational expenditure	OPEX
Small and medium enterprises	SMEs
Tobacco Products Directive 2014/40/EU	TPD
Unique identifier	UI
Value added tax	VAT
WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products	FCTC Protocol
WHO Framework Convention for Tobacco Control	FCTC

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1 INTRODUCTION

1.1 Background

On 3 April 2014, the European Parliament and the Council adopted the Tobacco Products Directive 2014/40/EU (hereafter: TPD).[1] The overall objective of the TPD is to approximate the laws, regulations and administrative provisions of the Member States concerning rules governing the manufacture, presentation and sale of tobacco and related products. It facilitates the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people. In addition, Article 1 of the TPD explicitly refers to the obligations of the European Union (EU) under the WHO Framework Convention for Tobacco Control (FCTC).[2]

Articles 15 and 16 of the TPD **aim at fighting illicit trade**[3] in tobacco products and thus at contributing to reducing the circulation of tobacco products not compliant with the TPD and other tobacco control legislation, as well as reducing artificially cheap supplies of illegal tobacco products that have been found to affect the uptake and general prevalence of smoking. Market statistics indicate an increase in the percentage of the illicit trade in cigarettes for the years 2005-2015 (see Table 1).

	2005	2010	2011	2012	2013	2014	2015
Total sales in million sticks	767,748	676,015	645,147	617,695	573,766	555,441	546,208
Illicit trade in million sticks	58,120	69,829	65,323	67,184	63,593	64,179	61,512
% penetration of illicit trade	7.6%	10.3%	10.1%	10.9%	11.1%	11.6%	11.3%

Table 1: *Illicit trade estimate of cigarettes (in EU25)*[4]

Articles 15 and 16 of the TPD **provide for the establishment of systems of traceability and security features for tobacco products**.

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1 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1), http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf

2 See: http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf?ua=1The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health Assembly in May 2003 and is the first international treaty on public health developed in response to the globalisation of tobacco consumption. The FCTC includes both demand reduction provisions (such as price and tax measures, protection from exposure to tobacco smoke, content and disclosure of tobacco products, packaging and labelling, education and communication, advertising, promotion and sponsorship) and supply reduction provisions (such as illicit trade, sales to and by minors and support for economically viable alternative activities).The FCTC is a legally binding instrument which needs to be implemented and enforced by all Parties having ratified the Convention, including the EU and its Member States.

3 For a more detailed breakdown of the categories of illicit tobacco trade see section 1.2.

4 These figures exclude Cyprus, Luxembourg and Malta. Based on Euromonitor data from 2015. (Figures updated and corrected as compared those set out in the Inception Impact Assessment on implementation of Articles 15 and 16 of the TPD, published at http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_694_695_696_ia_da_tpd_en.pdf. These changes have no bearing on the subsequent analysis)

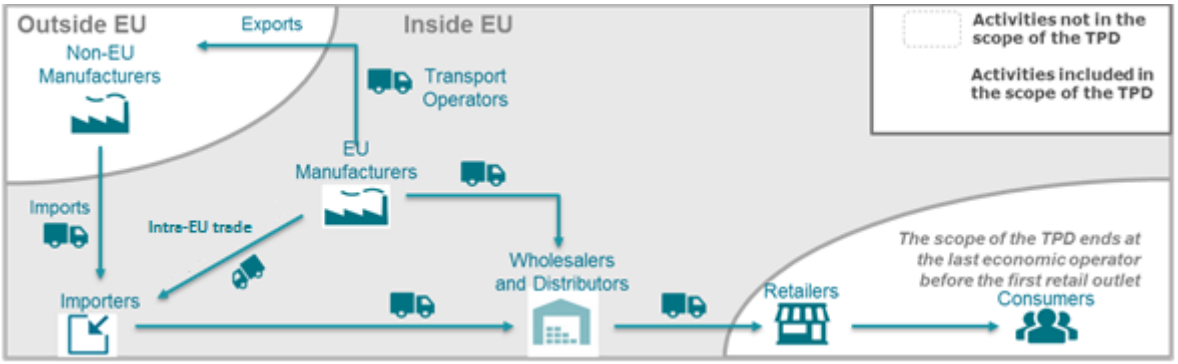

Figure 1: *Tobacco supply chain*

The provisions relating to **traceability** set out in **Article 15 TPD** require all unit packets of tobacco products manufactured in or imported into the Union to be marked with a unique identifier (i.e. UI, containing defined data elements)[5] and their movements to be recorded throughout the supply chain (up to the last economic operator before the first retail outlet, see Figure 1).[6] This identifier is unique for every unit packet, allowing for its individual identification.[7] The recorded movements are to be transmitted to and stored by an independent data storage provider (with which manufacturers and importers shall conclude data storage contracts, to be approved by the Commission).[8] The storage providers are required to be monitored by an external auditor and the data made accessible to the competent authorities of the Member States and the Commission.[9]

The provisions relating to the **security feature** set out in **Article 16 TPD** will facilitate the authentication of tobacco products, not only for competent authorities but also for consumers. Article 16 requires all unit packets of tobacco products placed on the EU market to carry a tamper proof security feature composed of visible and invisible elements, in order to facilitate the verification of whether or not they are authentic.

The systems for traceability and security features must be in place by 20 May 2019 for cigarettes and roll-your-own tobacco products, and by 20 May 2024 for all other tobacco products.[10] This will enable manufacturers of other tobacco products (which are often small and medium enterprises (SMEs)) a longer period to adapt and to benefit from the experience gained before the system becomes applicable to them.

The implementation of the traceability system provided for under Article 15 of the TPD will also enable the EU to fulfil its obligations under **Article 8** of the **WHO FCTC**

5 Article 15(2) TPD.
6 *Ibid.*
7 Article 15(5) also provides for marking and recording at aggregated packaging levels, such as carton, master case and pallet level, provided the tracking and tracing of all unit packs remains possible. 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 facilities. 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 master cases contained in it would be placed into a new pallet).
8 Article 15(8) TPD.
9 *Ibid.*
10 Article 15(13) TPD.

Protocol to Eliminate Illicit Trade in Tobacco Products (hereafter: FCTC Protocol),[11] a legally binding instrument based on Article 15 of the FCTC. The EU and its 28 Member States are Parties to the FCTC and the EU ratified the FCTC Protocol in June 2016. One of the key measures of the FCTC Protocol is the establishment of a global tracking and tracing regime (Article 8), consisting of national and/or regional systems. In order to ensure international interoperability of the various national/regional systems (which are likely to be developed differently by Parties depending on their national/regional context), the Protocol provides for a 'global information-sharing focal point', to be managed centrally by the FCTC Secretariat. Parties will be obliged to ensure that traceability information is made available to this focal point upon request, thereby enabling enquiries to be made and relevant information to be received.

It is Article 15 of the TPD that will implement the traceability system required under the FCTC Protocol in the EU. Due regard must therefore be given to its provisions in the preparation of the implementing legislation provided for under the TPD. It should be borne in mind that the FCTC Protocol requires each tracking and tracing system to be *controlled by the Party* who establishes it.[12] In all cases, therefore, overall control of the system should be with the authorities,[13] and it is crucial that the structure of the system to be established in the EU ensures this.

In order to define key technical specifications necessary for the establishment and operation of the systems of traceability and security features, as well as to ensure interoperability across the EU, Articles 15(11) and 16(2) of the TPD require the Commission to lay down implementing acts determining technical standards:

1) for the establishment and operation of the traceability system, including:
    a. marking packages with a UI;
    b. recording and transmitting data;
    c. processing, storing and accessing data.[14]
2) for ensuring that the systems used for the UI and the related functions are fully compatible with each other across the EU.[15]
3) for the security feature .[16]

As the establishment of systems for traceability and security features for tobacco products is required under Articles 15 and 16 of the TPD, the scope of the present Impact Assessment is limited to identifying and assessing a number of alternative policy options available to the Commission to meet its technical implementing obligations.

In order to conduct this assessment, the Impact Assessment draws on a variety of sources. These are described in detail in Annex 1 and include external expertise (a Feasibility Study regarding EU systems for tracking and tracing of tobacco products and for security

[11] See: http://apps.who.int/iris/bitstream/10665/80873/1/9789241505246_eng.pdf?ua=1&ua=1 The Illicit Trade Protocol was adopted by the Conference of the Parties to the FCTC in November 2012 and will enter into force on the 90th day following the ratification of the 40th Party to the Protocol. At the time of drafting, 28 Parties has completed full ratification, including the European Union and six EU Member States: France, Austria, Portugal, Spain, Latvia and Lithuania.

[12] Article 8(2) FCTC Protocol.

[13] The notion of control is reflected in the principle of independence laid down in Recital 31 TPD.

[14] Article 15(11)(a) TPD.

[15] Article 15(11)(b) TPD.

[16] Article 16(2) TPD.

features;[17] an Implementation Study on the technical specifications and other key elements for a future EU system for traceability and security features), consultation with stakeholders (targeted[18] and public[19] consultations; workshops;[20] meetings with Member States[21]), as well as independent technical and legal analysis. It should be noted that an important source for the analysis of impacts set out in section 5 of this document was the second interim report of the above-mentioned Implementation Study. The relevant findings of this study, including a detailed cost-benefit analysis of the policy options, are set out in Annexes 5 and 6.

Another key source and starting point for the current analysis was the impact assessment that accompanied the original TPD proposal.[22] The methodology employed in the TPD's impact assessment has to a large extent been replicated in the current document, in particular in relation to the calculation of social benefits as set out in sections 5 and 6, and with respect to the assumptions made regarding the effectiveness of the future systems of traceability and security features. Such an approach was deemed essential for ensuring consistency and robustness of the current analysis, and allows for gauging the potential contribution of the various policy options under consideration to achieving the overall TPD objectives.[23]

In addition to the Commission's obligations under Articles 15(11) and 16(2), Article 15(12) of the TPD empowers the Commission to adopt delegated acts to define the key elements of the data storage contracts that manufacturers and importers of tobacco products should conclude with an independent third party, as required under Article 15(8) of the TPD. Following careful consideration of the regulation guidelines[24] it was concluded that it would not be necessary to include this analysis in the current impact assessment, in particular given that what remains for the Commission to define under this act is unlikely to have significant economic, environmental or social impacts beyond those of the policy options currently under assessment,[25] and certain elements are likely to concern compliance of the contracts with specific Union and national law.[26] Finally, the suitability, independence and technical capacity of the third party selected, as well as of the data storage contract to be signed by it, are required to be approved on a case-by-case basis by the Commission.[27]

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17 See https://ec.europa.eu/health/sites/health/files/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

18 See http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en

19 See http://ec.europa.eu/health/tobacco/consultations/2016_traceability_security_features_en

20 See http://ec.europa.eu/health/tobacco/consultations/2016_stakeholderworkshop_tpd_en; http://ec.europa.eu/health/tobacco/2017_stakeholderworkshop_tpd_en

21 See http://ec.europa.eu/health/tobacco/events_en#anchor4

22 See Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, SWD(2012) 452 final, http://ec.europa.eu/health/sites/health/files/tobacco/docs/com_2012_788_ia_en.pdf

23 See also Annex 7

24 See http://ec.europa.eu/smart-regulation/guidelines/tool_5_en.htm

25 Most of the key elements of the data storage contracts, where not already defined in the TPD (such as access rights to the repository [Article 15.8 TPD]; information to be stored; possibility to modify or delete recorded data [Article 15.9 of the TPD]) are inseparably related to the content of the implementing acts for which the current impact assessment is being carried out (i.e. technical specifications for transmitting, processing and accessing stored data).

26 Such as the protection of sensitive information and personal data

27 Article 15(8) TPD.

The establishment of a traceability system **by legislative means**, i.e. Article 15 of the TPD complemented by the implementing and delegated acts to be adopted by the Commission under Articles 15(11) and (12) of the TPD, will also enable the EU to ensure, at the stage of designing the traceability system, that there is no possibility for obligations assigned to a Party to be performed by or delegated to the tobacco industry, in line with Article 8(12) of the FCTC Protocol.

1.2 Broader policy context and reasons to act

Illicit trade is broadly defined as any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase, including any practice or conduct intended to facilitate such activity. Illicit trade takes different forms. The main categories of tobacco products traded illicitly are contraband tobacco products (i.e. legally produced products which have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination), counterfeit tobacco products (i.e. brand protected products which have been falsified without consent of the brand owner and are not in compliance with the legal requirements in the destination jurisdiction) 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 in compliance with requirements in the destination jurisdiction). Illicit products may be also sourced from illicit manufacturing within a given jurisdiction.

The availability of illicit tobacco products strongly undermines the objectives of the TPD, as well as of EU tobacco control policy more generally. Firstly, illicit tobacco products are less likely to be in compliance with product regulation provisions, meaning that consumers do not benefit from key public health measures such as those provided for in the TPD.[28] Secondly, illicit tobacco products contribute to smoking initiation and facilitate tobacco consumption, in particular for young people, by providing a cheaper and more affordable source of tobacco products than the legal supply chain.

The implementation of Articles 15 and 16 of the TPD aims at reducing the availability of illicit supplies by increasing the security of the legal supply chain.[29] The traceability system provided for under Article 15 will enable the movement of legal tobacco products to be monitored (tracking) and allow the public authorities to determine at which point a product was diverted into the illicit market (tracing).[30] The security feature system provided for under Article 16 will facilitate authentication of unit packs of tobacco products, not only by competent authorities but also by consumers.

In thus exercising a control function on the legal supply chain, the traceability and security features systems will contribute first and foremost to addressing the issue of contraband tobacco products, i.e. those legally produced but diverted into illicit trade.

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[28] Including health warning and ingredients provisions etc.

[29] The adoption of measures to secure the supply chain in order to fight illicit trade of tobacco products is mentioned as well in the Communication from the Commission to the Council and the European Parliament, Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy, Brussels, 6.6.2013, COM(2013) 324 final, p. 15.
The Commission recently published a Progress Report on the implementation of the 2013 Communication (Brussels, 12.5.2017, COM(2017) 235 final): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017DC0235&from=EN

[30] COM(2013) 324 final, p. 10.

It should nevertheless be underlined that the systems may play a role in addressing other forms of illicit tobacco trade (counterfeit and illicit white tobacco trade), including by enabling authorities to recognise and identify normal and abnormal product flows and fluctuations. Given that an abrupt fluctuation (e.g. a sudden decrease in legal sales of certain tobacco products in a given area) may indicate that significant quantities of illicit products have begun to circulate (whether contraband, counterfeit or 'illicit whites'), such information will be a useful tool for Member States and will enable them to take appropriate investigative measures where necessary.

The below case studies provide examples of how the systems provided for under Articles 15 and 16 of the TPD may contribute in practice to addressing the various forms of illicit tobacco trade.

Traceability and security feature case studies: contraband, counterfeit and illicit white

- Case study 1: A dispatch truck fails to arrive at its next expected destination along the supply chain. By accessing the stored traceability information, authorities will be in a position to determine where the last recorded movements of the products in question took place. This will help to pinpoint the exact point of diversion (contraband).
- Case study 2: Regular dispatches to a specific retail outlet are suddenly cancelled or significantly reduced at the request of the retailer, due to reduced demand. By accessing the stored traceability information, authorities will be able to monitor such unexpected fluctuations and investigate whether they are due to increased circulation of illicit products in the area concerned (for example sale of counterfeit or illicit white products in a certain area/by a certain retailer).
- Case study 3: Tobacco products which do not carry security features, or whose security features have been tampered with, compromised or are otherwise non-compliant, are identified by consumers and/or owners of retail outlets in which they are placed on the market. The consumers and/or retailer outlet have been alerted to the fact that these products are likely to have emanated from illicit trade and are in a position to take appropriate action and inform authorities.

It is recalled that the consumption of tobacco products is related to serious negative consequences (health risks such as various cancer types, cardiovascular problems, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc.). Their treatment costs more than EUR 25 billion a year. The associated further productivity loss is estimated at EUR 8 billion a year. Last but not least, tobacco is the most significant cause of premature death in the EU, responsible for almost 700,000 deaths every year.[31]

Reducing illicit trade will contribute to strengthening the internal market in lawful tobacco products, and ensure lawful trade occurs within a regulatory framework that takes account of the objective of ensuring a high level of public health, thus alleviating the burden on

[31] TPD Impact Assessment, p. 1-2, 15.

health budgets for Member States. In addition, a side effect of the reduction of illicit trade will be an increase in budget revenues from the taxes on tobacco products.[32]

A 2012 study estimated the amount of duty that EU tax administrations lose to illicit trade at about EUR 11.1 billion a year.[33] Were illicit trade to be eliminated, it has been estimated that tax revenues would increase in the range of EUR 6.1 billion to EUR 7.2 billion a year[34] (after discounting for decreases in the tobacco consumption of artificially cheaper illicit products, according to the principles of price elasticity[35]).

The establishment of a traceability system will also support wider EU efforts to fight illicit trade in tobacco.[36] As the key measure to secure the supply chain, it forms part of the comprehensive EU strategy to step up the fight against cigarette smuggling and other forms of illicit trade in tobacco products.[37] In addition, synergies and complementarities with other EU systems can be envisaged, and combined use by authorities of the future traceability system with existing systems such as the Excise Movement and Control System (EMCS) – a computerised system for monitoring the movement of excise goods under duty suspension in the EU – has the potential to improve the overall monitoring capacity of EU authorities, increase the amount of data at their disposal and allow for cross-comparison of information. This in turn will generate positive synergies in combatting illicit trade, given that exchange of information is central to the fight against fraud.

As mentioned, one of the principle reasons for action stems from the need to fulfil the EU's legal obligations under the FCTC Protocol, a task which the EU has fully committed to via its 2016 ratification of the Protocol. Related to this is the potential for the EU's implementation to positively influence the FCTC Protocol ratification process in general. Ratification by a total of 40 Parties is required for the Protocol to enter into force. While this process has been completed by more than half of the required number of Parties, there remains a significant way to go.[38] The development of a traceability system by the EU – which will be among the first Parties to implement the Protocol's tracking and tracing requirements (as well as the first to develop a system across multiple countries i.e. all EU Member States) – may encourage further ratifications, not only by remaining EU Member States[39] but by third countries and regions, who will be in a position to draw on the EU's

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[32] The relevant EU legislation consists of the Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco.

[33] 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 (Ramboll Study), see: https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/ramboll-tobacco-study.pdf

[34] *Ibid.*

[35] Demand for tobacco products exhibits price elasticity, i.e. the quantity demanded responds to a change in the price of tobacco products. Higher prices generally lead to lower consumption. This effect explains the difference between the tax gap calculated on the basis of the size of illicit market and the expected revenues under the scenario in which artificially cheap illicit products are fully eliminated and partially replaced with correctly priced licit products.

[36] It should be noted that both DG TAXUD and OLAF have participated in the Inter-Service Group on Traceability and Security Features (led by DG SANTE), and that DG SANTE is a member of the Inter-Service Group on the Structure and Rates of Excise Duties Applied to Manufactured Tobacco (led by DG TAXUD), as well as the Inter-Service Group on the Progress Report on the 2013 Communication (led by OLAF).

[37] COM(2013) 324 final.

[38] 28 ratifications completed at the time of last revision (July 2017). See: https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4-a&chapter=9&lang=en

[39] 6 EU Member States had completed ratifications at the time of last revision (July 2017).

experience. As the EU has been a key player in developing the tracking and tracing obligations under the FCTC it is well placed to continue to play a vital role in this respect.

Finally, while in the past the EU and the Member States have concluded legally binding anti-contraband and anti-counterfeit agreements with the four largest tobacco manufacturers, the aims of which were to reduce the number of contraband and counterfeit tobacco products smuggled into the EU,[40] a decision not to renew the first of these agreements – with PMI – following its expiry in 2016 was recently taken by the Commission. This followed a technical assessment by the Commission of the experience with the PMI agreement which found that, though it had made an important contribution to the fight against PMI illicit trade, the market and legislative framework had changed significantly since its entry into force. The assessment concluded that the TPD and the FCTC Protocol were now the best instruments with which to fight against illicit trade in the EU.[41]

[40] Philip Morris International (signed in 2004 and expired on July 2016); Japan Tobacco International (signed in 2007, due to expire in 2022); British American Tobacco (Holdings) Limited (signed in 2010, due to expire in 2030); Imperial Tobacco Limited (signed in 2010, due to expire in 2030). In 2016 the European Commission decided not to renew its agreement with Philip Morris International.

[41] Technical assessment of the experience made with the Anti-Contraband and Anti-Counterfeit Agreement and General Release of 9 July 2004 among Philip Morris International and affiliates, the Union and its Member States, SWD(2016) 44 final https://ec.europa.eu/anti-fraud/sites/antifraud/files/technical_assessment_pmi_24022016_en.pdf and https://ec.europa.eu/anti-fraud/investigations/eu-revenue/philip_morris_international_2004_en

2 DEFINITION OF THE ISSUES

2.1 What are the main issues to address?

The purpose of this Impact Assessment is to identify and assess a set of alternative policy options capable of enabling the Commission to meet its implementing obligations relating to the establishment and operation of systems for traceability and security features, as provided for under Articles 15 and 16 of the TPD.

The main issues which these options must address can be broken down as follows:

1. The need to determine technical standards for the traceability system, including:
    a. marking packages with a UI;
    b. recording and transmitting data; and
    c. processing, storing and accessing data.
2. The need to determine technical standards to ensure full compatibility of components of the traceability system.
3. The need to determine technical standards for security features.

Issues 1 (**a. b**. and **c.**) **and 2** stem from the **traceability system requirements** under **Article 15 TPD**. In a workable traceability system, these issues will be closely interlinked: the marking of a tobacco pack with a UI, which will contain the information required under Article 15(2) TPD, will be the first step in the process (issue 1a). Economic operators will have to read this UI at all subsequent points in the supply chain (until the last point before the first retail outlet) in order to ensure that information on all of the product's movements is recorded and transmitted to a data storage facility (issue 1b), where it will be processed and made accessible to authorities for monitoring and enforcement purposes (issue 1c). (In this way, they will be provided with an overview of all tobacco product movements in the EU, making it possible for them to identify instances of illicit trade and take appropriate action). In order to ensure that the system operates smoothly, key technical compatibility requirements must be put in place (issue 2), in particular to ensure that all economic operators are in a position to record (scan) the required information.

Figure 2 below illustrates how these issues should combine and interact in a functioning traceability system.

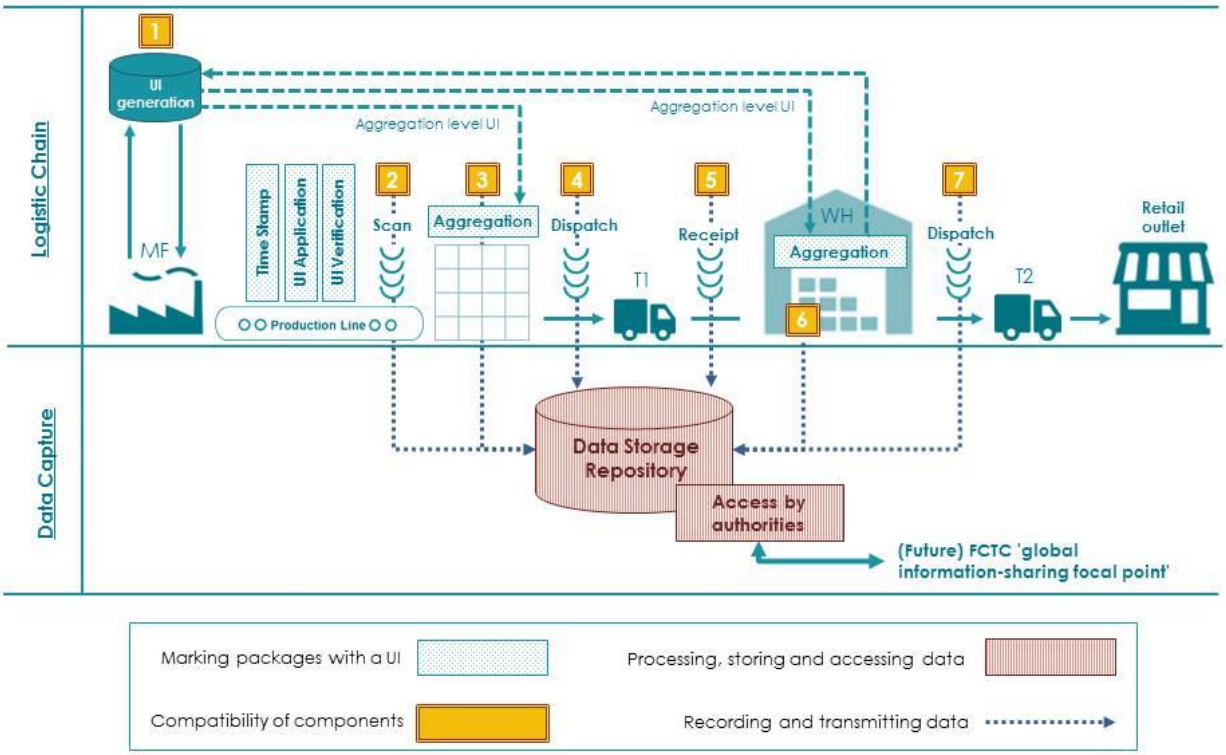

Figure 2: *Illustrative workflow of issues and their interaction in a working traceability system*

Issues 3 stems from the **security feature requirements** under Article 16 TPD. It is important to highlight that this is a separate and distinct issue from those relating to the traceability system under Article 15. The requirement for unit packets of tobacco products to carry security features is intended as an additional means (on top of the traceability system requirements) of verifying whether or not the products are authentic,[42] not only for authorities but also for consumers. It is also the only issue that does not stem from FCTC Protocol requirements. For this reason, it is necessary to treat it independently.

Further details relating to the questions to be addressed under each issue are set out below.

Issue 1a: Marking packages with a unique identifier (UI)
This issue is at the core of the traceability system. In order to track and trace tobacco products, it is necessary to mark each packet with a UI containing defined data elements (such as date and place of manufacturing, intended retail market etc.), as set out in Article 15(2) of the TPD. The marking is the basis for all subsequent steps performed within the

[42] Recital 29 TPD

traceability system. The process of marking with a UI can be broken down into the following main sub-tasks:

- *generation* of a part of the UI, providing for its uniqueness (i.e. through serialisation)[43]
- *application* of the UI on packs (i.e. printing/affixing),
- *optical verification* of its correct application (i.e. scanning the UI to ensure it is correctly applied).

A proper assignment of responsibility for each of these tasks amongst the various parties involved in the operation of the traceability system is central in order to provide for an effective system, ensure the required full control by the competent authorities (as required under the FCTC Protocol) and prevent potential manipulation. Various potential task allocation arrangements are presented under policy options 1a/1, 1a/2 and 1a/3.

Issue 1b: Recording and transmitting data

Once products are marked with UI, a key task is the recording and transmission of information on their subsequent movements. Article 15(5) of the TPD specifies that Member States shall ensure that "*all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession*". Article 15 further clarifies that this information must be transmitted to a data storage facility.

A key consideration in this context, given the nature and objectives of the system, as well as the need to avoid the possibility of manipulation, is the time that elapses between the occurrence of a reporting event (e.g. dispatch from facility; arrival at subsequent facility; aggregation of unit packs/disaggregation of unit packs etc.) and the transmission of the related information to the data storage system(s). Article 15 does not define precise modalities in this respect. Alternative maximum permitted time limits are presented under policy options 1b/1, 1b/2 and 1b/3.

Issue 1c: Processing, storing and accessing data

Following the recording and transmission of product data (issue 1b), the question of how it should be processed, stored and subsequently accessed by competent authorities becomes crucial. A system architecture that is capable of enabling easy upload of data by all relevant economic operators, providing secure storage of that data and offering full accessibility to it for competent authorities, as required under Article 15 of the TPD, is necessary to guarantee effective monitoring and enforcement. Alternative system architectures are presented under policy options 1c/1, 1c/2 and 1c/3.

Issue 2: Compatibility of components of the traceability system

[43] The remaining information necessary to complete the UI (as set out in Article 15(2) TPD) will need to be added at a second stage (e.g. information which may not be possible to foresee in advance of production, such as such as production shift/time of manufacture). The addition of this information will not, however, affect the uniqueness of the identifier. These parts should be clearly defined.

The Commission is required to determine technical standards to ensure that components of the traceability system are fully compatible with each other (e.g. along the supply chain, across Member States etc.).[44] These standards should facilitate the process of recording and transmission of product data for relevant supply chain actors (who will need to ensure compatibility with external components such as scanning devices) by ensuring that the information contained in the UI is encoded on packs in a pre-defined manner via data carriers[45] (e.g. barcodes). The authorised variety of data carriers should therefore be clearly defined.

It should be noted that Article 15(5) of the TPD also provides for the marking and recording of aggregated packaging, such as cartons, mastercases and pallets, provided that the tracking and tracing of unit packs remains possible. As all events entailing aggregation, disaggregation and re-aggregation of unit packs along the supply chain will need to be recorded, and the related information transmitted to the data storage facility, it will be necessary to foresee the placement of UIs also at aggregated packaging levels, as outlined in the figure below:

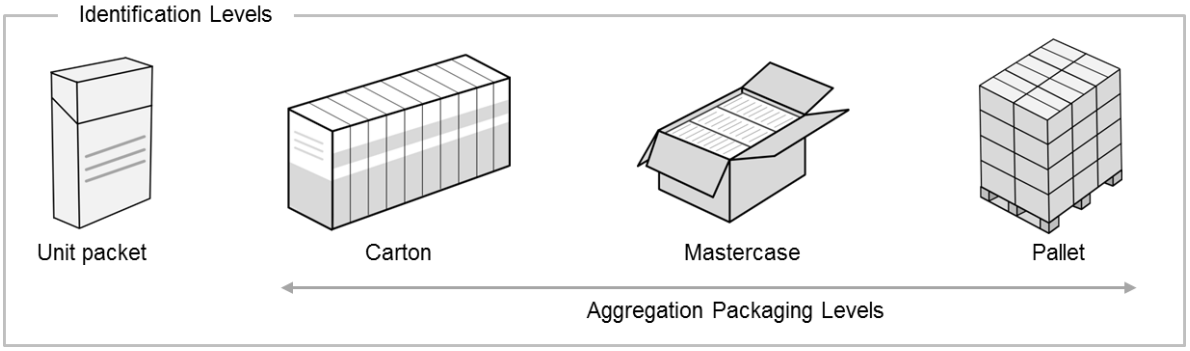

Figure 3: *Unit pack and aggregation levels*

The various alternatives are presented under policy options 2/1, 2/2 and 2/3.

Issue 3: Security features

The TPD requires all unit packets of tobacco products placed on the EU market to carry a tamper proof and indelible security feature, composed of visible and invisible elements.[46] In general, security features may be composed of one or a number of authentication elements (e.g. special inks visible in ultraviolet or infra-red, watermarks, high-tech micro-prints, chemical, biological and electronic taggants, holograms, security threads, etc.), which may be combined to generate a complete security feature meeting the requirements of Article 16 TPD.

The method of applying security features on packs is important for ensuring that they are able to fulfil their authentication function and meet the requirements of the TPD, in

[44] Interoperability is also a key consideration of Recital 30 TPD.

[45] A data carrier can be defined as a medium that holds machine-readable data. Data carriers come in different designs and types e.g. one dimensional (1D) barcodes, two dimensional (2D) barcodes, electronic cheap sets and radio frequency transmitters.

[46] Article 16(1) TPD. This requirement is separate from the requirement under Article 15 to carry a UI, and is intended to facilitate verification of whether or not unit packs of tobacco products are authentic, not only for competent authorities but also for consumers.

particular the requirement to be irremovable, indelible and tamper-proof. The chosen method should take into account different manufacturing processes and packaging types, the need to allow for future innovation and technological developments capable of enhancing the security feature, as well as the needs of consumers and enforcement authorities. The alternative policy options are presented under options 3/1 and 3/2.

2.2 How would the main issues evolve, all things being equal? – Baseline scenario

Though exact figures for illicit tobacco trade penetration are difficult to establish, overall levels remain high, as confirmed by a recent progress report.[47] Illicit trade in cigarettes as a percentage of total trade is estimated to have amounted to 11.3 % in the EU in 2015.[48] In addition, there are significant variations across EU countries: some Member States have witnessed decreases while others have witnessed increases in recent years.[49] It has been estimated that in some Member States the illicit market share may exceed one quarter of the entire tobacco market.[50]

Concerted efforts to fight illicit trade, in particular by means of tracking and tracing, have been scarce at Member State as well as at international level. The Impact Assessment of the TPD **outlined** how national legislation to address illicit trade in tobacco products is not harmonised across the EU.[51] Without EU action, it is likely that Member States would adopt different national solutions. This would not only hinder the functioning of the internal market, but lead to different levels of monitoring and enforcement, as well as to interoperability issues, which would be detrimental to the proper functioning of the measures and to the supply chain.

Where the marking of tobacco products has taken place in the past, this has most commonly been carried out by tobacco industry, using the system developed, owned and operated by it. This system has not been developed with a view to meeting the specific legal requirements of independence and control set out in the TPD and FCTC Protocol. According to the WHO FCTC Secretariat, the industry system conflicts with the FCTC Protocol and does not meet the requirement of Article 8.2 for the tracking and tracing system to be "controlled by the Party".[52]

At international level, currently three countries (Brazil, Kenya, and Turkey) have implemented specific marking systems for tobacco products intended to comply with the requirements of Article 8 of the FCTC Protocol. The EU closely monitors these developments, notably in the context of information-sharing practices under the FCTC. Further details relating to their operation are set out in Annex 10. The national contexts of these systems, however, differ significantly from that of the EU, which is in many respects unique: not only is the EU's system required to comply with the specific legal framework set out in the TPD, but it must be capable of operating across its multiple Member States. It is therefore necessary for the EU to develop solutions suitable for its specific situation.

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47 COM(2017) 235 final, p.7.
48 See Table 1.
49 Based on Euromonitor 2015 (these figures exclude Cyprus, Luxembourg and Malta).
50 COM(2017) 235 final, p.8.
51 Impact Assessment of the TPD, p. 38.
52 http://www.who.int/fctc/protocol/faq/en/index2.html

Traceability requirements have recently been introduced in the EU in the field of pharmaceutical products.[53] This system aims to reduce the number of falsified medicines circulating in the EU and represents a concrete example of traceability from the health sector which, like the traceability system for tobacco products, is enforcement-driven. Nevertheless, important differences between the two exist which make direct comparison difficult: the system envisaged for medicinal products foresees a 'check-in, check-out' (or end-to-end) verification system, rather than the recording of all intermediate supply-chain movements as is the case for tobacco products, and the scanning of aggregated packaging levels is not provided for. Finally, the system for medicinal products is not yet fully operational, making it difficult at this stage to draw on the system's practical experience.

The failure of the EU to take action would also lead to a significant regulatory gap, given the recent decision (outlined in section 1.2) not to renew the first of the legally binding anti-contraband and anti-counterfeit agreements with the four largest tobacco manufacturers, following its expiry in 2016. [54] Such a decision was based on a clear presumption of future action on the part of the EU to implement the systems provided for under the TPD and the FCTC Protocol.

All of the **above** further underlines the need for timely implementation of Articles 15 and 16 of the TPD in the EU. In the absence of this, the current high levels of illicit trade of tobacco products are likely to persist or increase. This would negatively affect the free circulation of compliant products and also undermine the objective of a high level of health protection pursued by the TPD.

From a legal perspective, the absence of action at EU level would render it very difficult for Member States to meet their obligations under Articles 15 and 16 of the TPD in a workable and interoperable manner, namely to ensure the tracking and tracing of all unit packs of tobacco products and their marking with a security feature. It would in addition significantly increase the difficulty for Member States to meet their obligations under the FCTC Protocol, not least the requirement to make the traceability information of each Party available to the 'global information-sharing focal point' foreseen under Article 8 of the FCTC Protocol.

2.3 Does the EU have the right to act and is EU added value evident– Treaty base, 'necessity test' (subsidiarity)

This initiative implements Articles 15 and 16 of the TPD. The power to adopt implementing acts is conferred upon the Commission by these articles. A subsidiarity check was already carried out in the Impact Assessment of the TPD and compliance with the principle has been confirmed by the Court of Justice of the EU.[55]

In the absence of the adoption of these acts, the Commission would not meet its obligations under the above mentioned provisions.

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[53] Commission Delegated Regulation 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

[54] https://ec.europa.eu/anti-fraud/sites/antifraud/files/technical_assessment_pmi_24022016_en.pdf and https://ec.europa.eu/anti-fraud/investigations/eu-revenue/philip_morris_international_2004_en

[55] Judgment of 4 May 2016, *Philip Morris Brands and others* (C-547/14) ECLI:EU:C:2016:325.

In addition, the EU, as Party to both the FCTC and the FCTC Protocol, has committed to establishing a tracking and tracing system for tobacco products.[56] **The EU's implementation of its traceability system for tobacco products may encourage ratification by remaining EU Member States as well as third countries, thereby contributing to accelerating the entry into force of the FCTC Protocol.**

2.4 Who is affected, in what ways, and to what extent?

A list of affected stakeholders and related information is set out in Annex 8.

[56] Article 8(2) FCTC Protocol.

3 OBJECTIVES

3.1 General objective

The general objective of this initiative is to **implement the systems for traceability and security features provided for under Articles 15 and 16 of the TPD, and thereby to** address the issue of illicit trade in tobacco products, which undermines the free circulation of products compliant with the TPD and other tobacco control legislation.

3.2 Specific objectives

The specific objectives of the implementing acts can be summarised as follows:

- ensure effective tracking and tracing for tobacco products within the EU.
- ensure an effective system of security features for tobacco products.
- ensure international interoperability of the EU's traceability system with the future global tracking and tracing regime provided for under Article 8 the FCTC Protocol.

In all cases, the assessment of effectiveness must take into account the need to ensure the ability of authorities to oversee the establishment and operation of the systems, and the extent to which national enforcement activities are facilitated.

3.3 Operational objectives

The operational objectives of this initiative have been identified with the aim of developing appropriate solutions for the five main issues referred to in section 2.1:

- Issue 1a: 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 (objective 1a).
- Issue 1b: 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 (objective 1b).
- Issue 1c: 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** (objective 1c).
- Issue 2: to ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers (objective 2).
- Issue 3: to facilitate the authentication of tobacco products by an optimal selection of application methods for security features (objective 3).

A relationship table linking the main issues with the operational objectives and the policy options presented in future sections can be found in Annex 4.

It should be recalled that Article 15 of the TPD sets out the key requirements for tobacco products to be tracked and traced throughout the Union, leaving to the Commission the task of developing technical standards related to the practical establishment and operation of the system. This impact assessment identifies and addresses the main issues (listed above) not directly addressed in the basic act but central to achieving full system functionality.

4 POLICY OPTIONS

In order to ensure that the issues referred to in section 2.1 are properly addressed and achieve the operational objectives set out in section 3.2, several policy options have been identified.

These policy options were initially based on input received from external expertise (the Feasibility Study)[57] and further developed by the Commission (Inception Impact Assessment).[58] In parallel, in order to test the policy options, as well as to gain the key views of stakeholders (Member States; economic operators; non-governmental organisations; solution providers; the general public), a series of consultation exercises was undertaken.[59] Further external expertise was also sought (Implementation Study)[60] and legal and independent analysis was carried out.

Based on this input, the options have been further adapted,[61] in particular to take into account the realities of the supply chain, the enforcement needs of competent authorities, the burdens that may reasonably be imposed on different operators and the need to make the systems adaptable to future technological developments and innovation.

With respect to the latter point, where possible across the policy options the use of open, non-proprietary standards has been included and technical specifications are set out in general terms instead of via specific requirements that may undermine flexibility or favour proprietary technologies.[62] Open standards and generalised technical specifications play an important role in allowing systems to keep up to date with technological advances. This is crucial for their effective functioning over time and for preventing them from being locked into specific or proprietary technologies and solutions. Such an approach also contributes to stimulating competition and innovation in the market.

It should be noted that such an approach was widely favoured across stakeholders groups throughout the consultation process and is therefore considered to be beneficial for economic operators and public authorities, as well as for the long-term viability of the systems.

In relation to the traceability system provided for under Article 15, it should be noted that all policy options should be capable of enabling it to achieve the basic system functionality illustrated in figure 4 below.

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

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

59 A full overview of procedural steps, including external expertise and consultation exercises, is provided in Annex 1.

60 *Ibid*.

61 Certain policy options have been added, removed or modified as compared to those examined at previous phases in the process (such as Inception Impact Assessment phase). For previous versions of the policy options, see Annex 1.

62 For example, while the content and format of the product information messages that economic operators will be required to transmit should be clearly set out in the implementing legislation, none of the policy options presented below entails the prescription of a particular technology or protocol with which to ensure transmission. Economic operators will be free to decide on the solutions depending on their capacity to meet the system requirements.

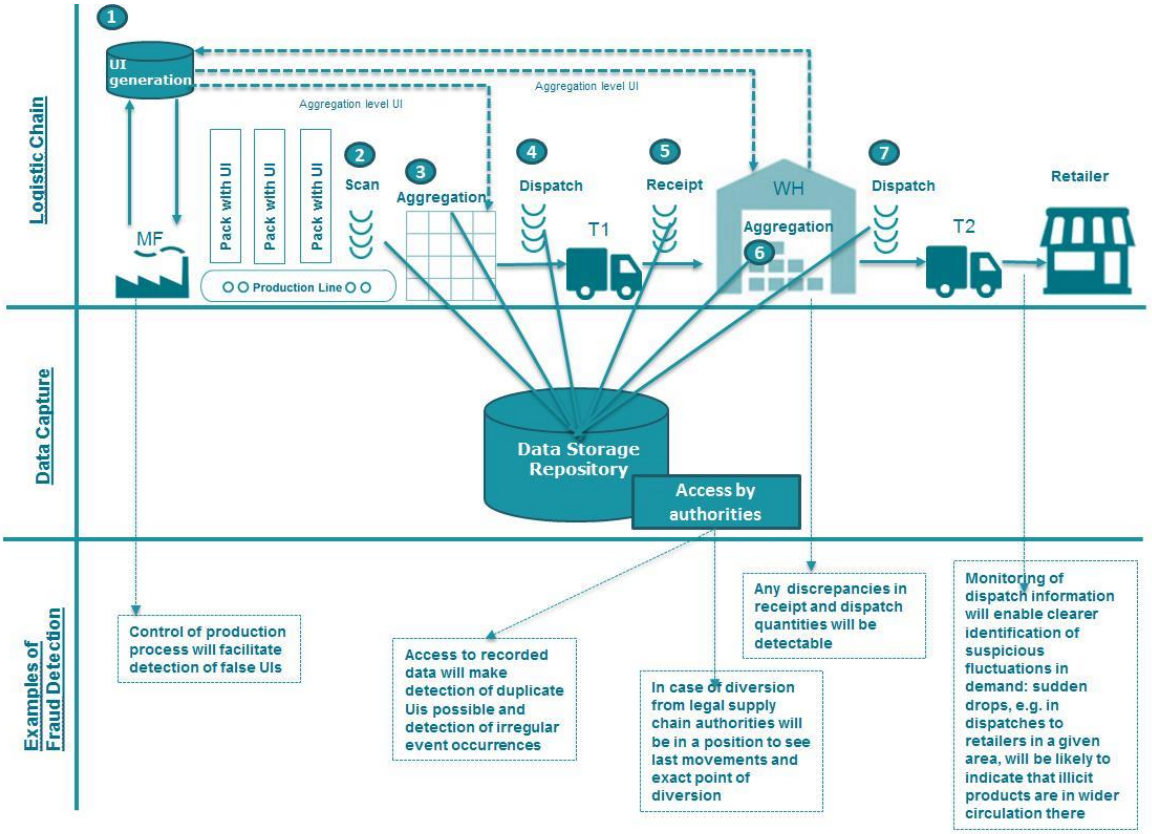

Figure 4: *Flowchart of a functioning traceability system including use cases*

A set of options for each of the main issues identified in section 2.1 is presented below.

4.1 Marking packages with a unique identifier (Issue 1a)

4.1.1 Policy options for achieving objective 1a: 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

As explained above, the process of marking tobacco packs with a UI consists of:[63]

- generation of a part of the UI, providing for its uniqueness (i.e. through serialisation);[64]
- application of the UI;
- optical verification of the UI.

The TPD remains silent as to the task allocation of these main functions, but reference is made to ensuring the independence of the traceability system.[65] In addition, the FCTC

[63] See section 7.1 of the Implementation Study, Annex 5.

[64] The remaining information necessary to complete the UI (as set out in Article 15(2) of the TPD) will need to be added at a second stage (e.g. information which may not be possible to foresee in advance of production, such as such as production shift/time of manufacture). The addition of this information will not, however, affect the uniqueness of the identifier. These parts should be clearly defined.

[65] Recital 31 TPD.

Protocol stipulates that the system must be controlled by the Parties. This means that competent authorities must be able to control, supervise and direct all relevant actions. This approach does not exclude the possibility for other actors to operate and perform a sub-set of activities that are necessary for the effective functioning of the system, as long as competent authorities maintain full control of the system.

Against this background, and given the various levels of the supply chain (as illustrated in Figure 3 below), the allocation of roles and tasks concerning the above main functions of marking tobacco packs with a UI must be clearly defined.

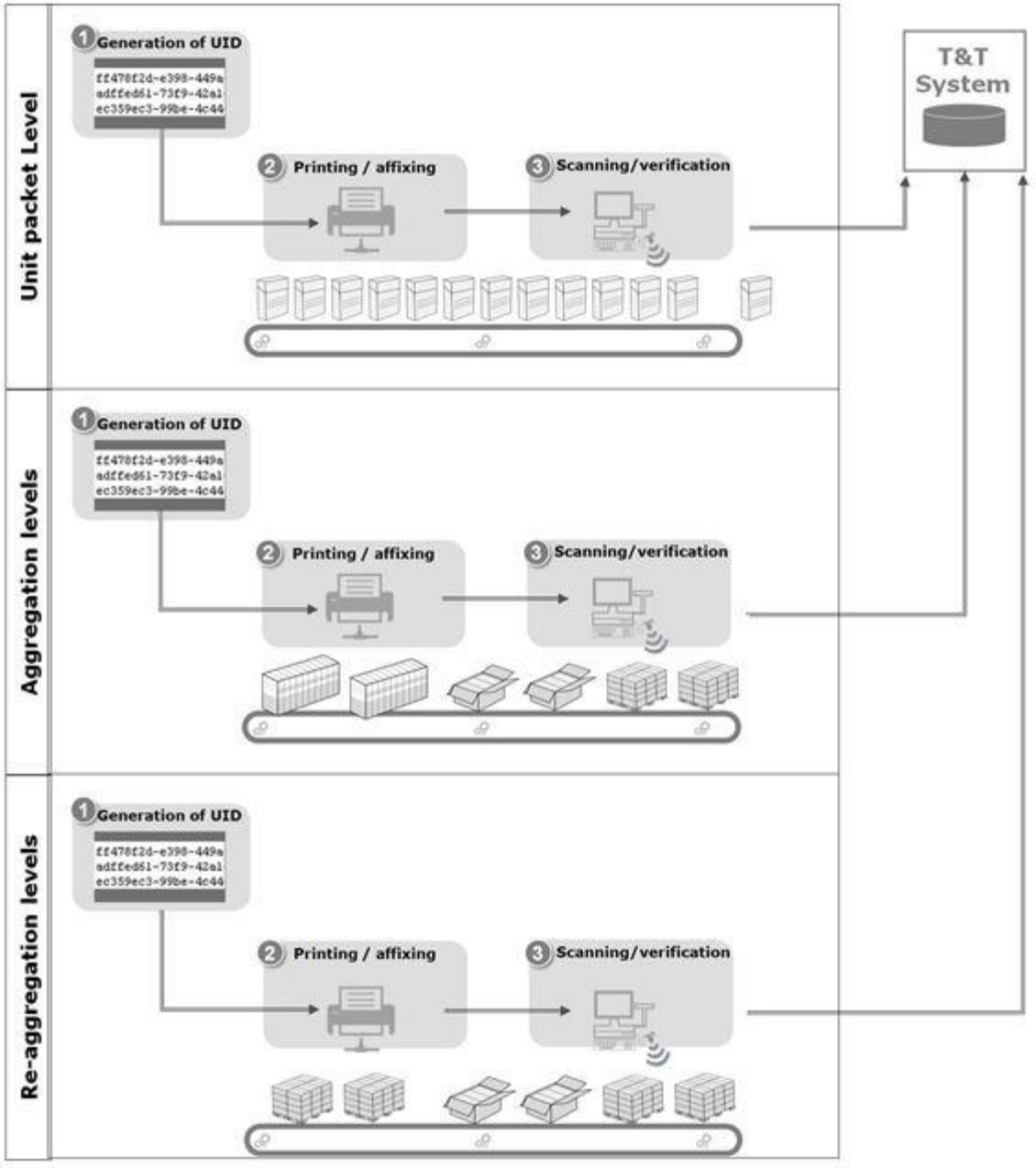

Figure 5: *Activities related to marking packages with a unique identifier*

It should be recalled that UIs will need to be applied not only at unit pack level but also at aggregated packaging levels (see Issue 2, section 2.1), and that in such cases the above sub-

tasks – generation, application and optical verification – must also be performed. UIs for aggregated packaging levels should primarily enable identification of the unit packs contained within the aggregation[66] – e.g. by listing or linking to their UIs.

The policy options below set out the alternatives for the allocation of roles and tasks.

4.1.2 Policy option 1a/1: Industry operated solution

Under this option manufacturers and importers[67] of tobacco products are responsible for all three sub-tasks identified above, both at the level of unit packets as well as for any aggregated packaging produced at the manufacturing facility. Where aggregation (or re-aggregation) of unit packs is carried out by subsequent supply chain operators, such as distributors, the operators in question would be allowed to generate UIs themselves, or request them from the manufacturer. These operators would then be responsible for applying and verifying them on the aggregated packaging.

Nevertheless, as all three key sub-tasks related to marking with a UI are performed by the industry under this option, it would be necessary to set in place extensive control mechanisms to ensure the independence of the system and its full control by the competent authorities. The execution of these extensive controls would be the responsibility of the competent authorities and may involve their own presence or the presence of an appointed third party in the manufacturing facilities.

4.1.3 Policy option 1a/2: Third party operated solution

Under this option, independent third parties, with no link to the tobacco industry, are responsible for carrying out all three sub-tasks identified above. The independence and technical capabilities of the third parties would be assessed by the competent authorities. The independent third parties would require permanent access to the production facilities in order to install and operate their equipment on the production lines.

Distributors and operators at subsequent points along the supply chain would be allowed to apply and verify UIs on the aggregated packaging themselves, after receiving them from an independent third party.

4.1.4 Policy option 1a/3: Mixed solution (industry and third party)

This option proposes dividing responsibility for the different sub-tasks between the tobacco industry, supply chain operators and independent third parties. This division of the tasks would be such as to allow competent authorities (via the independent third parties) to control, supervise and direct all relevant actions of the system, whilst permitting sub-tasks of a more technical nature to be carried out by the economic operators. The division of tasks under this option means that, **in the case of unmarked packages of genuine products found in circulation,** economic operators **would remain fully and directly accountable.**

[66] Tracking and tracing of unit packs must remain possible, according to Article 15(5) TPD.

[67] Importers are legally responsible for assuring the conformity with the requirements of Article 15 TPD before the imported products enter into the EU territory. It is assumed that most of importers will meet their obligations by requiring their suppliers to apply unique identifiers directly on the non-EU production lines.

Based on discussions with experts and relevant stakeholders, the **generation of a part of the UI** (providing for its uniqueness) has been identified as the sub-task most fundamental to system control, as it provides control over the supply of identifiers, offers the possibility to ensure their uniqueness and best protects against manipulation.

Under the mixed solution, independent third parties, with no link to the tobacco industry, would be responsible for the generation of a part of the UIs for all packs (both unit packs and aggregated levels). The independence and technical capabilities of the third parties would be assessed by the competent authorities. Independent third parties would not require permanent access to the production facilities but would be requested to install anti-tampering devices (such as surveillance cameras) on production lines in order to provide for additional checks. The parts of the UIs generated would be transferred by the independent third parties to manufacturers and importers upon request, via secure channels.

Manufacturers and importers would be made responsible for sub-tasks of a more technical nature; i.e. application and verification of UIs.

Distributors and operators at subsequent points along the supply chain would be required to request UIs for aggregated packaging levels from the third parties and to subsequently apply and verify them.

It should be pointed out that, as independent third parties will not be in a position, time wise, to obtain from the manufacturers all the information necessary to form the UI (as set out in Article 15(2) of the TPD), such as time of manufacture, the remaining information would need to be completed on site by the manufacturer (or distributor/operator). These parts should be clearly defined.

It should be noted that although this option presents a more complex division of tasks than the previous options outlined, its technical feasibility has been confirmed in analysis by experts.[68]

4.2 Recording and transmitting of data (Issue 1b)

4.2.1 Policy options for achieving objective 1b: 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

The TPD requires all economic operators involved in the tobacco product supply chain (from the manufacturer to the last economic operator before the first retail outlet) to record all movements relating to unit packets of tobacco products – including the entry into possession, intermediate movements and final exit from possession – and transmit this data to the relevant data storage facility. In order to enable competent authorities to carry out their surveillance and enforcement activities effectively, in particular in cases in which it is necessary to take rapid action, up-to-date information relating to product movements should be available to them.

In order to ensure this, it is necessary for information on the movement of products (or 'events') to be recorded and transmitted to the data storage facility in as timely a manner as

[68] See section 7.1.2. of the Implementation Study, Annex 5.

possible. Maximum permitted time lags between the occurrence of an event (e.g. the scanning of a UI upon application; the dispatch of products from a facility; the arrival of products at a subsequent facility; aggregations performed by economic operators etc.) and its transmission to the data storage by economic operators should therefore be defined.

Three possible options have been identified: a near real-time, once daily or once weekly time lag. A longer time lag would not allow for attainment of the policy objective identified as it would no longer be possible to effectively monitor the movements of products.

4.2.2 Policy option 1b/1: Near real-time

This option proposes a minimum permitted (near real-time) time lag between a supply chain event and its recording and transmission to the relevant data storage by an economic operator.

Real-time reporting requirements are often in the order of several seconds. However, in order to provide some margin for the internal processes of economic operators, this policy option foresees a near real-time requirement (e.g. transmission to data storage facility up to a number of hours after an event occurrence). Economic operators would be allowed to process the event in their internal systems and would then be required to transmit the related information to the data storage facility by the elapse of the set time lag. Competent authorities would receive regular reports containing smaller data volumes.

4.2.3 Policy option 1b/2: One day time lag

This option proposes a maximum permitted time lag of 24 hours between a supply chain event and its recording and transmission to the data storage facility by an economic operator. Relevant processing of the event data by the economic operator's internal system could take place during this time and competent authorities would expect to see once-daily transmissions to the data storage. This would result in the need for economic operators making use of the 24 hour permitted time lag to locally store and later transmit a larger amount of data (compared to option 1b/1), which could be transmitted in batches.

4.2.4 Policy option 1b/3: One week time lag

This option proposes a maximum permitted time lag of 7 days between a supply chain event and its recording and transmission to the data storage by an economic operator. Relevant processing of the event data by an economic operator's internal system could take place during this time and competent authorities would expect to see once-weekly transmissions to the data storage. This would result in the need for economic operators making use of the 7 day permitted time lag to locally store and later transmit a larger amount of data (compared to option 1b/1 and 1b/2), which could be transmitted in batches.

4.3 Processing, storing and accessing data (Issue 1c)

4.3.1 Policy options for achieving objective 1c: 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

In order to ensure effective surveillance and enforcement activities, the TPD stipulates that the Commission, the national competent authorities and the external auditor shall have full access[69] to the data which is recorded, transmitted to and subsequently stored within the facilities of an independent third party.[70] By accessing the data stored, competent authorities will have the possibility to systematically monitor the movement of tobacco products throughout the supply chain ("tracking"). In addition, at the time of any inspection it will be possible to recreate the route taken by the product and to determine at what point it was diverted into illicit trade ("tracing").

In this context, the architecture of the storage system, the means by which data can be processed and stored by it and the ease with which competent authorities can access it are key aspects to be defined.[71] Three policy options have been identified in this respect: a decentralised model per manufacturer/importer, a decentralised model per Member State and a combined model that is decentralised for recording (per manufacturer/importer) but which comprises a common copy of data providing for read access by the competent authorities of the Member States, at centralised level.

It should be pointed out that both the Inception Impact Assessment and the Feasibility Study had identified the establishment of a single centralised data storage as an additional alternative option. Following further scrutiny of the relevant legal provisions, as well as careful consideration of the input received from stakeholders,[72] a decision not to retain the option of a single centralized data storage was taken. The current impact assessment instead adopts an approach based on the establishment of technical standards to ensure that the data storage contracts effectively serve the purpose for which they are intended – namely to ensure an effective and independent system for the traceability of tobacco products – but are nevertheless capable of providing authorities with the global overview and ease of access to the stored data necessary.

It should be noted that the above approach does not exclude the possibility for manufacturers to freely opt for one single data storage provider for the EU.

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69 Article 15(8) TPD.

70 *Ibid.*

71 As far as data storage technologies are concerned, the system requirements are not envisaged to go beyond the specifications of systems currently used in many economic sectors. See also section 10 of the Feasibility Study.

72 Certain stakeholders, in particular manufacturers of tobacco products, strongly supported a decentralised storage architecture during the consultation process.

4.3.2 Policy option 1c/1: Establishment of a decentralised model as per manufacturer/importer

This policy option provides for the establishment of multiple independent data storage repositories organised per manufacturer or importer (i.e. decentralised). It leaves the choice of independent data storage provider to each manufacturer or importer. In all cases the suitability of the third party must be approved by the Commission.[73]

In order to ensure that information recorded by economic operators is correctly processed, this option provides for a data router service run by an independent third party and responsible for ensuring the transmission of data to the correct data storage facility. Furthermore, to ensure that the required access to the stored data is granted to the Commission, the competent authorities of the Member States and the external auditor, as provided for in Article 15(8), this option includes the creation of a central query tool (called 'discovery service' in Figure 4 below) run by an independent third party and linked with all decentralised repositories. This would allow authorities to address queries relating to the data stored in all individual repositories (e.g. similar to using a system with access to all libraries in the EU to identify the location of a particular book). The query tool would not permanently store any traceability data but would facilitate data searches (in contrast to option 1c/3 below).

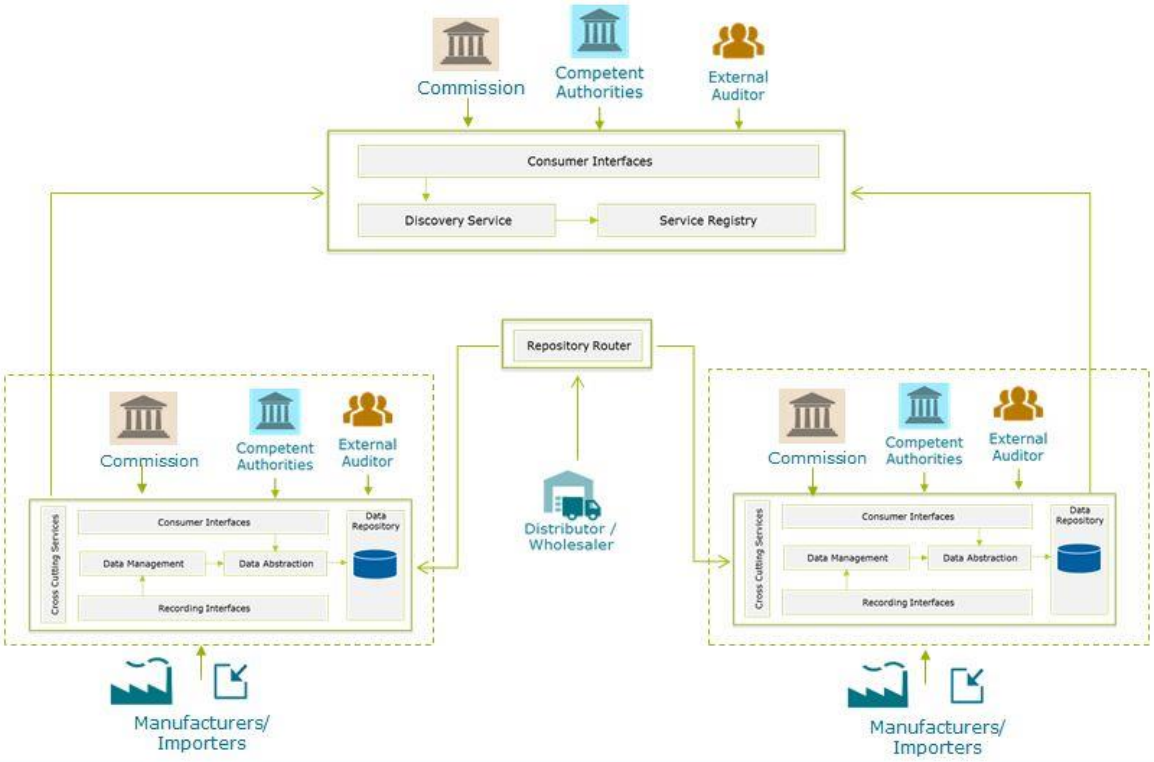

Figure 6: *Decentralised model per manufacturer/ importer*

4.3.3 Policy option 1c/2: Establishment of a decentralised model per Member State

This policy option proposes the establishment of one data storage repository per Member State. Each repository would host data exclusively related to the Member State in question,

[73] Article 15(8) TPD clarifies that the suitability of the third party refers in particular to its independence and technical capacity.

i.e. related to tobacco products manufactured and/or placed on the market in that Member State, and/or imported into the EU on its territory. For this purpose, each Member State would be responsible for the identification of an independent data storage provider which would host data related to it, and with which each (relevant) manufacturer or importer would sign a contract.

To ensure the required access to the stored data by the Commission, the competent authorities of the Member States and the external auditor, as provided for in Article 15(8), this option provides for the creation of a central query tool run by an independent third party and linked with the national repositories, similar to that described under policy option 1c/1. Such a central query tool would allow competent authorities to analyse data hosted in the repository of other Member States (thereby allowing Member States to, inter alia, verify products merely in transit across their territory).

To ensure the transmission of data to the correct data storage facility, this option provides for a router service, similar to that described under the policy option 1c/1.

4.3.4 Policy option 1c/3: Establishment of a combined model: decentralised for recording per manufacturer/importer with centralised surveillance

This policy option provides for the establishment of a data storage system which is composed of multiple decentralised repositories, organised per manufacturer/importer, as well as for a central surveillance solution, including a single centralised data storage repository, run by an independent third party, which can be commonly accessed and viewed by Member States. The main difference as compared to policy options 1c/1 and 1c/2 is that the central element stores a copy of all data transmitted to the individual decentralised repositories in one common data repository (see Figure 5). The presence of this single central data repository, managed by an independent third party and made accessible to all Member States, would provide competent authorities with a global overview of the supply chain, not limited to the specific "search question" necessary under the central query tool system in the options above. This would enable Member States to ensure full access according to Article 15(8) of the TPD.

To ensure the transmission of data to the correct data storage facility, this option provides for a router service, similar to that described under the previous policy options.

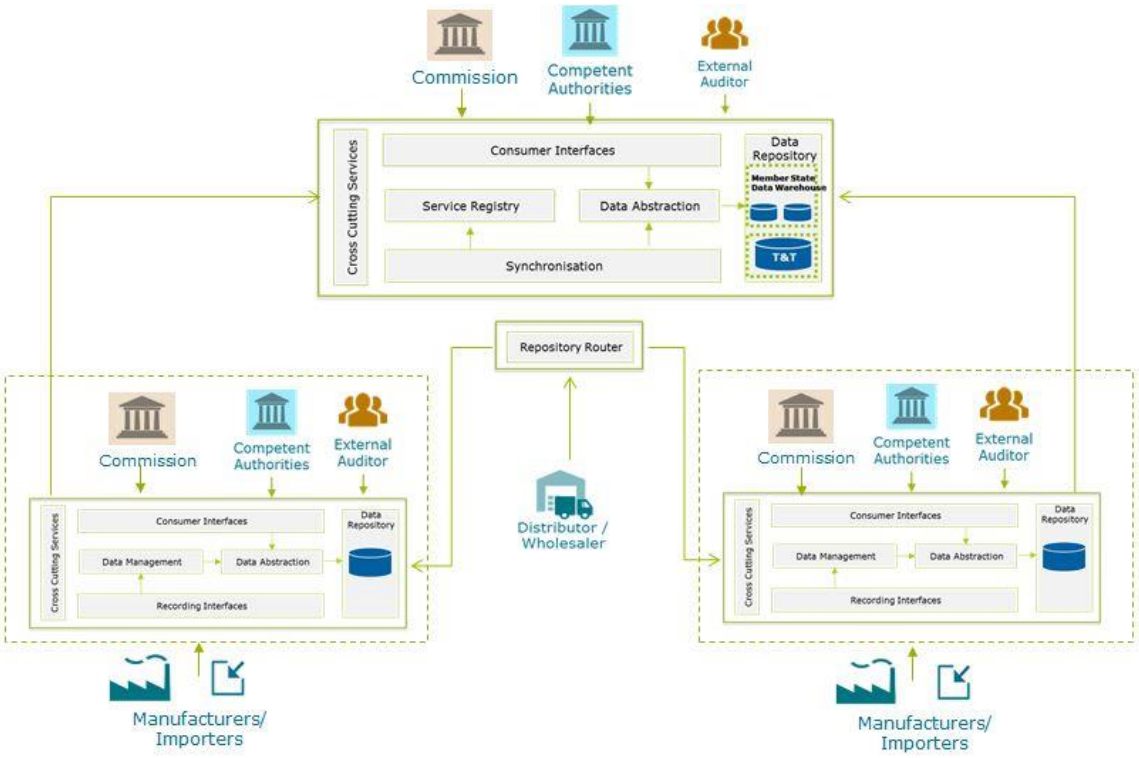

Figure 7: *Combined model - centralised for surveillance and decentralised for recording (per manufacturer/importer)*

4.4 Compatibility of components of the traceability system (Issue 2)

4.4.1 Policy options for achieving objective 2: To ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers

Marking with data carriers (which contain the UIs), such as barcodes, will take place at unit packet as well as aggregated packaging level. To assure effective identification of products, a data carrier must be able to hold a UI containing all the required information.[74]

Technical specifications relating to data carriers are central for ensuring readability of all information required under Article 15 of the TPD across the supply chain and by all actors. This further guarantees the interoperability of the system. Three alternative policy options have been identified. It should be noted that in order to ensure full compatibility, it will be essential for data carriers to use open standards based on non-proprietary solutions, so that they are available to all operators.[75]

[74] The unique identifier marking the unit pack shall allow for determining the information stipulated in Article 15(2) TPD. The unique identifiers applied at aggregated levels will need to be unequivocally related to lower levels including the unit pack, but are not subject to the same information requirements.

[75] Several data carriers have already been made subject to international standards, e.g. ISO/IEC 16022:2006 (Data Matrix) and ISO/IEC 18004:2015 (QR Code)

4.4.2 Policy option 2/1: Single data carrier per level

This option proposes a single authorised data carrier per packaging level, i.e. one data carrier for unit pack level, and one separate data carrier for carton, mastercase and pallet level respectively.[76]

Manufacturers and importers would need to adjust their machinery to apply and read the authorised data carrier, depending on the packaging levels being produced/imported. Wholesalers and distributors would have to make use of scanners that are capable of reading the authorised data carrier for aggregation levels, and competent authorities carrying out inspections would have to do likewise for all packaging levels.

4.4.3 Policy option 2/2: Limited variety of data carriers per level

Under this option, economic operators may choose from a limited number of authorised data carriers per packaging level, i.e. a limited number of data carriers for unit pack level, and a separate limited number for carton, mastercase and pallet levels respectively (overlaps in the authorised data carriers per level are likely).[77]

Manufacturers would need to adjust their machinery to at least one data carrier from the limited authorised list. Wholesalers and distributors would have to make use of scanning devices that are capable of reading all the authorised data carriers for aggregation levels, and competent authorities carrying out inspections would have to do likewise for all packaging levels.

4.4.4 Policy option 2/3: Free system allowing any existing data carrier

This option proposes that any data carrier may be placed on the unit pack and at aggregation levels, as long as it is able to hold a UI containing all the required information.

Manufacturers would therefore need to select at least one type of data carrier meeting the necessary requirements and adjust their machinery accordingly. Conversely, wholesalers and distributors, as well as competent authorities carrying out inspections, would need to ensure that they use scanners capable of reading all data carriers available on the market.

4.5 Security features (Issue 3)

4.5.1 Policy options for achieving objective 3: to facilitate the authentication of tobacco products by an optimal selection of application methods for security features

The method of applying security features on packs is important, in particular given that different packaging types (e.g. paper, wood etc.) may require different application methods. An important additional consideration is that Article 16 of the TPD permits Member States to allow the use of tax stamps or fiscal markings for the security feature, provided they meet the requirements of that article (including those to be laid down via implementing acts). It is important to ensure that future developments and innovation in the field of security feature technology, which may provide enhanced protection, are capable of being incorporated. The chosen method of applying security features to packs can play an important role in

[76] This option does not restrict the right of economic operators to place additional, not pre-defined data carrier(s) on packages, where necessary for internal logistic purposes, provided that this does not interfere with the prescribed data carrier(s) and all relevant labelling provisions are complied with.

[77] *Ibid*.

achieving this by widening the potential variety of authentication elements that may be used to form security features.

Further information relating to the two methods of adding security features provided for under Article 16 (printing or affixing) has therefore been sought via external expertise[78] and consultation.[79] The latter provided competent authorities, economic stakeholders and consumers with an opportunity to provide targeted input.

The Commission was provided with a useful overview of existing methods as well as insight into their feasibility and expected impact for different production lines. The needs of enforcement authorities were also clarified and potential future evolutions in the field of security feature technology were indicated.

It emerged as important that the technical standards to be laid down by the Commission ensure flexibility and avoid prescribing the use of specific authentication elements to form the security feature, an approach which would favour proprietary solutions and exclude the incorporation of technologies yet to be developed.

Taking this into account, two policy options were identified in line with Article 16: the first would allow a choice between printing and affixing of security features on unit packs. The second would extend this choice to permit, in addition to the above, a combination of the two methods, i.e. a security feature applied to unit packs via a combination of printing and affixing.

4.5.2 Policy option 3/1: Printing or affixing

Under this option there would be two possible methods for adding a security feature to unit packs.

Printing is the first of these, provided it is performed in a way that renders the feature irremovable. This requires the printing to take place directly on the unit pack (i.e. before it is wrapped in surrounding material such as cellophane). Under this method, it may be possible for the printing to be performed either on the manufacturers' production lines or at a previous stage (such as by the suppliers of packaging material).

Affixing is the other method by which security features could be placed on unit packs, provided it is performed in a way that renders the feature irremovable. This is likely to involve placing the security feature in an area where it is impossible to tamper with it without breaking or damaging the unit pack and/or the use of specific technologies (e.g. frangible papers). Affixing must take place directly on the unit pack and before it is wrapped in surrounding material such as cellophane. Affixing is currently the most common method by which Member States' tax stamps or fiscal markings are applied to packs.[80]

[78] See Annex 1 (parts on Feasibility Study, Implementation Study).

[79] See Targeted Stakeholder Consultation, Annex 2; Public Consultation, Annex 3.

[80] For the avoidance of doubt, for the purpose of Article 16 of the TPD, affixing is considered as a broader term than mere labelling. See further sec. 8.6.1 of the Implementation Study, Annex 6.

4.5.3 Policy option 3/2: Printing or affixing or a combination of printing and affixing

Under this option there would be three possible methods for adding a security feature to unit packs.

In addition to the two above-mentioned methods, the placing of security features on unit packs via a combination of both printing and affixing would be allowed. Under this third option, individual elements would be printed and affixed. A combined set of these elements would therefore form the security feature in the sense of Article 16 of the TPD.

5 ANALYSIS OF IMPACTS

The impact assessment analyses social and economic impacts of the policy options under evaluation. No particular environmental impacts have been identified. Impacts on fundamental rights (in particular the right to conduct a business) were already assessed in the Impact Assessment for the TPD, which constitutes the legal base for the establishment and implementation of systems of traceability and security features.[81] Likewise, the Impact Assessment of the TPD already included an assessment of trade impacts with respect to the implementation of the systems in question.[82]

Each of the discussed policy options differs not only in terms of costs, but also as regards their potential for attaining the reference level of social and economic benefits. The analysis set out in the following sections takes these differences into account, most importantly by assessing the extent to which the individual policy options and their measures

- are suitable to achieve the operational objectives set out in section 3;
- are necessary to achieve these objectives;
- allow these objectives to be achieved at maximum benefit and minimum costs.

All the positive impacts brought about by this initiative rely on the same explanatory variable, i.e. a decrease in the size of the illicit tobacco market. As to the negative impacts, the initiative is considered not to have adverse impacts in social terms since, as it will be explained, it has relatively low overall costs (estimated at a fraction of the expected benefits), a minimal impact on the unit costs and hence is not expected to affect employment in the legal supply chain. The negative economic effects are dependent on the costs of establishing and operating the system.

The figures provided are estimates and rely on the underlying assumptions of the key sources outlined in section 1.1 as well as on other available data. They should not be presumed to be exact but rather provide an indication of the order of magnitude expected for the various categories of costs and benefits. The clandestine nature of the illicit market makes it particularly difficult to make accurate predictions relating to its future trends or composition. The relative novelty of the traceability system may in turn affect the precision of cost estimates. Even if the individual aspects of the system are pre-dominantly based on currently used and tested technologies,[83] the system will be the first of its kind to operate amongst such a broad range of economic operators in a multi-national regulatory context.

Reference level of social and economic benefits

The analysis estimates the reference level of social and economic benefits expected to be delivered with this initiative at EUR 3.8 billion a year. This level serves as a reference point in the subsequent analysis of individual policy options, since the different options are not likely to attain the same level of benefits.

The initiative could generate a reduction in illicit trade equal to 2.45% of the total tobacco products market, which translates into 674 million cigarette packs per year.[84] It is assumed

[81] See TPD Impact Assessment, Part 1, section 2.4 (on EU basis to act), p. 43.

[82] See TPD Impact Assessment, Part 5, section A.4.1 (on assessment criteria of impacts), p. 1.

[83] For further details on the overall technical feasibility of a traceability system for tobacco products, see the Feasibility Study.

[84] 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 provided in Table 1. This is a conservative approach, which likely leads to underestimation of the total benefits brought about with the present initiative. See

that the initiative could result in an increase of the licit sales by 510 million cigarette packs per year and a decrease of the total consumption by 164 million cigarette packs per year.

A lower level of tobacco consumption is equal to a higher level of public health, increased number of healthy life-years and less suffering from tobacco related diseases affecting both smokers and their families. First and foremost, health must be considered a value in itself, both for the individual and for society as a whole. Following the methodology adopted in the TPD Impact Assessment, the main categories of social effects can also be monetised. 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.[85]

The expected increase of the licit sales may provide EUR 2 billion per year in collected taxes (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 the tobacco products. An increase in the quantities of legally traded tobacco products should have a positive effect in terms of employment within the tobacco sector. However, this effect is difficult to account for as it can also be expected that the traceability system will induce further automation in the production and logistic chain.

Table 2 summarises the reference level of expected direct economic and social benefits. It can be assumed that the full potential benefit will be achieved gradually over six years from the launch of the system, i.e. over the period 2019 to 2024.[86]

Benefit	Type	Affected stakeholders	Value (in EUR million per year)
Savings in healthcare expenditures	Social	Competent authorities	165
Social productivity gains	Social	Competent authorities	54
Saved lives	Social	General public	1497
Higher collection of taxes	Economic	Competent authorities	2029
Increased revenues of the economic operators	Economic	Manufacturers, importers, distributors, wholesalers and retailers	59
Total			3804

Table 2: *Direct social and economic benefits – reference levels*

The expected economic and social benefits vary across Member States. Their magnitude depends on several factors. These are: (a) the estimated size of the national markets for illicit products, (b) their composition in terms of different types of illicit products (i.e.

Annex 7 for further explanations on the calculation of the reduction in illicit trade and the reference level of social and economic benefits. For individual Member States the impacts differ according to different size and composition of the illicit sales on their respective territories. See section 9.1 of the Implementation Study, Annex 6.

[85] The relevant calculations followed the methodology adopted in the TPD Impact Assessment, SWD(2012) 452 final. See also sections 9.3 and 9.4 of the Implementation Study, Annex 6 and Annex 7.

[86] See section 5.1.1.1.1 of the Implementation Study, Annex 6.

contraband, counterfeit and illicit whites) and (c) differences in the assumed elasticity of demand reflecting income disparities across Member States. Together these factors translate into different relative and absolute changes in the consumption of legal products as well as in the reduction of the overall consumption at the national level. The magnitude of economic impacts is further affected by differences in prices and taxation across Member States. Table 3 shows the expected distribution of economic and social benefits per Member State.

	SB	EB		SB	EB		SB	EB		SB	EB
AT	30	104	EL	65	93	IE	20	74	PL	197	81
BE	31	37	ES	98	144	IT	85	122	PT	24	22
BG	33	18	ET	7	6	LT	16	7	RO	142	71
CY	na	7	FI	10	17	LU	1	5	SK	9	7
CZ	23	27	FR	346	508	LV	20	10	SL	6	9
DE	184	316	HR	na	10	MT	1	2	SV	18	38
DK	3	4	HU	68	12	NL	37	43	UK	241	293

Table 3: Direct social (SB) and economic (EB) benefits in EUR million per year per Member State

In terms of other effects, it is recalled that the illicit tobacco trade has been identified as a primary source of revenue for organised crime, and, in some case, terrorist groups. The European Agenda on Security adopted by the European Commission in April 2015 recognises the need to cut off criminal groups from this revenue source.[87] The present initiative has a potential of reducing such revenues by EUR 1671 million per year.[88]

The initiative is also likely to create positive unintended consequences in terms of competitiveness, innovation and job creation in the sector for traceability and security feature technologies. For track and trace solutions and security features to be effective in meeting their objectives, they must rely on the latest technological developments. Modern technologies (such as digitalisation of data, state-of-the-art developments in two-dimensional bar codes, modern printing technologies, encryption techniques and forensic technologies) will be further customised to match the specific needs of the tobacco sector. It is likely that the technologies developed during the EU deployment of the system will be to a certain extent taken over by non-EU countries, in particular in the context of the global implementation of the FCTC Protocol. These effects are not directly dependent on the policy options discussed below. However, they can be expected to positively correlate with the maximisation of the initiative's benefits, which will serve as a proof of concept and promote the technologies developed during the EU deployment.

Nature of costs

Given the nature of the traceability system, all the costs indicated under main issues 1-3 (section 5.1-5.4) and allocated to the economic operators should be considered as compliance costs, and in particular, as administrative burdens. The traceability system established under Article 15 of the TPD obliges economic operators until the last economic operator before the first retailer to report the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. The recording and transmitting of data clearly constitutes an information obligation. All the elements of the system serve this purpose.

[87] See http://ec.europa.eu/anti-fraud/sites/antifraud/files/docs/body/q_and_a_en.pdf

[88] See Commentary on the cost-benefit analysis, Annex 7.

Regarding the system for security features (Article 16 of the TPD) all costs discussed under the policy options proposed for main issue 4 (section 5.5) should be considered as substantive compliance costs.

Cost analysis

Each of the below policy options is evaluated by looking at its various impacts in terms of economic costs.

The costs are divided into capital expenditure (CAPEX) and operational expenditure (OPEX). Apart from the equipment, CAPEX also includes the costs of installation, installation support and implementation. In order to annualise the initial capital investment, CAPEX is depreciated over the period of six years. The depreciation allows for jointly reporting CAPEX and OPEX in terms of an annualised total cost for each of the options.[89]

The relevant costs are analysed per stakeholder group. However, it must be recalled that the majority of the costs will be eventually covered by manufacturers of tobacco products. Article 15(7) of the TPD stipulates that manufacturers provide all other economic operators with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The costs allocated to service providers are also to be covered by the manufacturers who will be required to conclude contracts with service providers whenever certain tasks are allocated to a third party, e.g. data storage.[90] Each instance of the cost redistribution is indicated in the below analysis.

5.1 Marking packages with a unique identifier (Issue 1a)

5.1.1 Policy options for achieving objective 1a: 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

The analysis of the policy options identified under objective 1a covers the following tasks:

- generation of UIs for unit packets and higher aggregation levels, i.e. cartons (10 packets), master cases (50 cartons) and pallets (50 master cases);
- application of UIs (encoded in a data carrier (e.g. barcode) to unit packets and higher aggregation levels;
- verification if the UIs have been correctly applied;
- audits and additional controls.

5.1.2 Policy option 1a/1: Industry operated solution

5.1.2.1 Economic impacts

Economic costs

In terms of economic costs, policy option 1a/1 affects (a) manufacturers and importers, (b) distributors and wholesalers and (c) competent authorities.

[89] For further comments on the cost analysis, please see commentary on the cost-benefit analysis, Annex 7.

[90] In this context, it must be recalled that Article 8(14) of the FCTC Protocol stipulates that *"each Party may require the tobacco industry to bear any costs associated that Party's obligations"*.

Manufacturers and importers[91]

CAPEX: EUR 69 million	OPEX: EUR 23 million	Annualised cost: 34 EUR million

During the consultations, this option was clearly preferred by the economic operators involved in tobacco trade as the most cost-efficient in terms of operations.

SMEs, in particular representing the cigar sector, argued that their unit costs are considerably higher due to the small scale of operations. However, no calculations were provided to substantiate this claim.[92]

The technical evaluation shows that this option could involve potential problems at the level of system interoperability, if multiple manufacturers are involved in the generation of UIs.[93]

Distributors and wholesalers[94]

CAPEX: EUR 21 million	OPEX: 1 EUR million	Annualised cost: 5 EUR million

It must be noted that these costs are applicable only insofar distributors and wholesalers need to re-aggregate products at higher packaging levels. The CAPEX element will be transferrable to manufacturers under Article 15(7) of the TPD.

During the consultations, many respondents underlined the importance of open standards for a cost-efficient roll-out and operations of the future system.

As regards SMEs, it seems plausible to assume that their costs will be alleviated if there is a competitive market of providers offering solutions tailored for smaller operations, such as off-the-shelf software packages or external generation of UIs.

Competent authorities[95]

CAPEX: n/a	OPEX: EUR 16 million	Annualised cost: EUR 16 million

During the consultations, non-industry respondents often recalled that competent authorities are obliged to be in control of the future system (under Article 8(2) of the FCTC Protocol) and stressed the importance of the system's independence from the industry as required by the TPD. For competent authorities to be able to control the system, this option includes a quasi-permanent presence of competent authorities at the manufacturing sites.

Economic benefits

The attainment of the reference level of economic benefits referred to above within the industry operated system is less probable given the nature of economic incentives faced by economic operators and their employees.

High profitability of illicit trade creates immediate economic incentives for misusing the traceability system, e.g. by duplicating identifiers or misreporting logistic events. In addition, the strong addictiveness of tobacco means that illicit trade may contribute to

[91] See section 8.2.4 of the Implementation Study, Annex 6.

[92] In this context, it is important to recall that most of SMEs are active in the production of other tobacco products than cigarettes and roll-your-own products and hence will be only obliged to establish the tracking and tracing system with a 5-year delay, which will enable them to benefit from the prior experiences. Second, SMEs will likely be able to rely on providers offering solutions tailored for smaller operations, e.g. off-the-shelf software packages or services of external generation of unique identifiers. Finally, the Commission's evaluation is bound by the TPD which does not allow for any carve-outs from the general obligation of establishing the tracking and tracing system.

[93] See item 2-1 in section 7.1.2 of the Implementation Study, Annex 5.

[94] See section 8.2.4 of the Implementation Study, Annex 6.

[95] See sections 8.2.3.3 and 8.2.3.4 of the Implementation Study, Annex 6.

creating new demand for legal products. Consumers initially prevented by their age or economic status from purchasing the legal tobacco products can be initiated with illicit products. But it is also likely that such consumers will eventually turn to the legal tobacco products.[96]

The consulted health NGOs have cited instances where the industry has been investigated for facilitating the supply of illicit tobacco.[97] Consequently, they stressed that the schemes designed or promoted by industry, or in which the industry takes a major role in implementation, should be regarded as inadequate.

The affected stakeholder groups are: competent authorities and economic operators along the supply chain, i.e. manufacturers, importers, distributors, wholesalers and retailer. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[98]

5.1.2.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits within the industry operated system is less probable.

The affected stakeholder groups are: competent authorities and general public. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[99]

5.1.3 Policy option 1a/2: Third party operated solution

5.1.3.1 Economic impacts

Economic costs

In terms of economic costs, policy option 1a/2 directly affects (a) independent service providers and (b) competent authorities. Subsequently independent service providers charge their costs to (c) manufacturers and importers and (d) distributors and wholesalers. As far as the CAPEX element is charged to distributors and wholesalers, they can in turn require manufacturers to reimburse this part of the costs under Article 15(7) of the TPD.

Independent service providers[100]

CAPEX: EUR 100 million	OPEX: EUR 25 million	Annualised cost: EUR 42 million

Independent service providers will charge their costs to the industry. The estimates are based on the same cost calculations as in option 1a/1 – i.e. the costs of manufacturers,

[96] See TPD Impact Assessment, p. 108-09.

[97] As an example of the recent potential problems with the industry's self-governance, the health NGOs referred to the case reported in the British press: https://www.theguardian.com/business/2014/nov/16/bat-fined-for-oversupplying-tobacco-in-low-tax-european-jurisdictions
Other examples are provided in:
- Beare, M. (2003) Organized Corporate Criminality: Corporate Complicity in Tobacco Smuggling. In BEARE M. (Ed.), Critical Reflections on Transnational Organized Crime, Money Laundering, and Corruption, University of Toronto Press, 183-206.
- Collin, J. et.al. (2004) Complicity in contraband: British American Tobacco and cigarette smuggling in Asia. Tobacco Control, 13, 104-111.

[98] See Table 2.

[99] *Ibid.*

[100] See section 8.2.4 of the Implementation Study, Annex 6.

importers and those of distributors/wholesalers – but increased with a 10% margin of independent service providers.[101]

Several respondents also drew attention to potential liability issues (e.g. costs of production stoppage) related to the presence of third parties (independent service providers) at the industry facilities.

The technical evaluation further indicates that the presence of a third party may negatively affect the manufacturing process.[102]

Competent authorities[103]

CAPEX: n/a	OPEX: EUR 2 million	Annualised cost: EUR 2 million

Under option 1a/2, competent authorities are not required to implement extensive control measures, regular audits are deemed sufficient. The audits cover both manufacturing facilities and activities of independent service providers.

The selection of independent service providers will call for an organisational effort limited to the initial phase of establishing the system. As a strict minimum, competent authorities will have to verify providers' independence.

Economic benefits

The attainment of the reference level of benefits within the third party operated solution is **highly probable**. In this policy option, the presence of an independent service provider[104] at the industry facilities provides for a high level of assurance against potential misuses of the system, which in turn could affect the system's overall performance.

The affected stakeholder groups are the same as in option 1a/1.

5.1.3.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits within the third party operated solution is **highly probable**.

The affected stakeholder groups are the same as in option 1a/1.

5.1.4 Policy option 1a/3: Mixed solution (industry and third party)

5.1.4.1 Economic impacts

Economic costs

In terms of economic costs, policy option 1a/3 affects (a) manufacturers and importers, (b) distributors and wholesalers, (c) independent service providers and (d) competent authorities. As in policy option 1a/2, independent service providers charge their costs to the economic operators involved in tobacco trade.

[101] The present analysis assumes the installation of new equipment on all production lines in order to provide a conservative estimate of the costs brought about with this initiative. However, this does not mean that the initiative will force the writing off of any pre-existing equipment that will meet the TPD requirements.

[102] See item 3-1 in section 7.1.2 of the Implementation Study, Annex 5.

[103] See section 8.2.3.4 of the Implementation Study, Annex 6.

[104] Independent service providers do not face the same economic incentives (described under option 1a/1) as economic operators involved in tobacco trade and their employees.

Manufacturers and importers[105]

CAPEX: EUR 76 million	OPEX: EUR 9 million	Annualised cost: 22 EUR million

The costs include the installation of anti-tampering devices for verification of UIs. These costs were assumed to be a part of the overall installation and configuration costs allocated to manufacturers and importers.

During the consultations, it was noted that this policy option does not affect the operations of hardware equipment on the production lines. The operations of hardware equipment alone are believed not to pose a risk to the system's integrity, while being highly prone to liability questions if they become dependent on third party actions. This option also excludes the need for extensive integration of economic operators' hardware with that of the third party, and hence is less technically complex than option 1a/2.

On the basis of the proposed allocation of tasks, the experts from Member States confirmed that this option represents a compromise that can ensure effective control, while respecting legal requirements.

The technical evaluation indicates that this option should have no negative impacts on the operational processes of manufacturers.[106]

Distributors and wholesalers[107]

CAPEX: EUR 21 million	OPEX: EUR 1 million	Annualised cost: EUR 5 million

The same impacts are expected as in policy option 1a/1.

Independent service providers[108]

CAPEX: n/a	OPEX: EUR 14 million	Annualised cost: EUR 14 million

Under policy option 1a/3, independent service providers are made responsible for the generation of UIs. Independent service providers will charge their costs to the industry. The estimates are based on the same cost calculations as in option 1/1 for the generation of UIs, but increased by a 10% margin of service providers.

During the consultations, manufacturers and certain solution providers argued that due to efficiency and security reasons, the generation of UIs should take place at the manufacturing line.[109]

The technical evaluation does not confirm this opinion. The security risks related to the generation of UIs do not vary whether performed by the industry or a third party. The key issue is whether adequate security is in place to protect the generating server.[110]

[105] See section 8.2.4 of the Implementation Study, Annex 6.
[106] See item 3-1 in section 7.1.2 of the Implementation Study, Annex 5.
[107] See section 8.2.4 of the Implementation Study, Annex 6.
[108] See section 8.2.4 of the Implementation Study, Annex 6.
[109] However, these comments do not appear to take into account a broad range of operators that will have to receive unique identifiers. The externalisation of this technological block will help SMEs, in particular small distributors and wholesalers, to comply with the TPD requirements. Moreover, the comments do not reflect the nature of the unique identifier required at the unit pack level by Article 15(2) of the TPD. The security risks related to potential interception will be largely limited by the specific nature of information included in the unique identifier.
[110] See item 5-1 in section 7.1.2 of the Implementation Study, Annex 5.

Competent authorities[111]

CAPEX: n/a	OPEX: EUR 2 million	Annualised cost: EUR 2 million

Under policy option 1a/3, competent authorities are not required to implement extensive control measures as in option 1a/1, regular audits are deemed sufficient. The audits cover both manufacturing facilities and activities of independent service providers.

The selection of independent service providers will call for an organisational effort limited to the initial phase of establishing the system. As a strict minimum, competent authorities will have to verify providers' independence.

Economic benefits

The attainment of the reference level of benefits in the mixed solution is **highly probable**. In this policy option, the involvement of an independent third party provides for a high level of control over the supplies of essential inputs, i.e. UIs, as well as for additional controls over outputs through the anti-tampering devices securing the process of optical verification of UIs. The proposed control measures provide for a high level of assurance against potential misuses of the system, which in turn could affect the system's overall performance. At the same time, the operation of hardware equipment (used in marking) by the economic operators **keeps them fully and directly accountable for any potential instances of unmarked packages of genuine products found in circulation.**

The affected stakeholder groups are the same as in option 1a/1.

Option 1a/3 also represents the most beneficial option in terms of unintended positive consequences for research and innovation as it promotes dynamic market competition for providing a range of services. There are numerous suppliers interested in this market as could be observed during the stakeholder workshops organised by the Commission.[112] In return, this can drive innovation, for example by stimulating further improvements in UI application and verification.

5.1.4.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in the mixed solution is **highly probable**.

The affected stakeholder groups are the same as in option 1a/1.

5.2 Recording and transmitting data (Issue 1b)

5.2.1 Policy options for achieving objective 1b: 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

The cost benefit analysis of the policy options identified under objective 1b reflects the system's requirements as to the recording and transmitting of data concerning the tracking and tracing events. Although the main parameter is timeliness of data transmissions, the

[111] See section 8.2.3.4 of the Implementation Study, Annex 6.

[112] For the reports from the stakeholder workshops, including the list of in-person participants, see: https://ec.europa.eu/health/tobacco/consultations_en.

cost calculations include the total costs of hardware and software development required for the recording and transmitting of data that take place under any scenario.

In all policy options, the affected stakeholders are economic operators obliged to report the movements of tobacco products, notably (a) manufacturers and importers and (b) distributors and wholesalers.

5.2.2 Policy option 1b/1: Near real-time

5.2.2.1 Economic impacts

Economic costs

Manufacturers and importers[113]

CAPEX: EUR 4 million	OPEX: EUR 2 million	Annualised cost: EUR 3 million

During the consultations, several stakeholders observed that real-time recording and transmitting of data is highly complex and its costs are very difficult to estimate. It requires automated synchronisation and data integrity checks of several sources of information, e.g. internal enterprise resource planning (ERP) systems, which are required to meet the reporting obligations introduced by Article 15 of the TPD. However, larger manufacturers admitted to already working in near real time except in situations of network failures. A few stakeholders pointed out that the real time solutions avoid potential problems with network congestion caused by upload of daily data batches. A distinction was 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.

Member States and several stakeholders stressed that in this option particular regard must be given to the needs of SMEs for which near real time compliance may be difficult to achieve.

The technical assessment confirmed the opinions expressed by the stakeholders that the implementation and operational complexity of this option needs to be considered.[114]

Distributors and wholesalers[115]

CAPEX: EUR 35 million	OPEX: 40 EUR million	Annualised cost: EUR 46 million

During the consultations, very similar comments concerning technical aspects were made as for manufacturers and importers. It was highlighted that many SMEs use the scanning equipment based on docking stations, which transfers information only once docked for synchronisation, i.e. not in real time. It will be very demanding for SMEs to introduce this option in time.

Economic benefits

Assuming that economic operators manage to introduce the near real time recording and transmitting of data, the attainment of the reference level of benefits in this option is **highly probable**.

Several non-industry stakeholders pointed out that only the real time option can guarantee to achieve the objectives of the traceability system. Any other option puts the ability to

[113] See section 8.5.5 of the Implementation Study, Annex 6.
[114] See items 1-1, 3-1 and 3-2 in section 7.4 of the Implementation Study, Annex 5.
[115] See section 8.5.5 of the Implementation Study, Annex 6.

effectively fight carrousel frauds, frauds in transit and diversion points at risk by allowing for time gaps.

Member States also agree that the shorter the timespan the more effective the ability of enforcement bodies to react to possible anomalies.

The technical evaluation further highlights the ability of a near real time solution to integrate most effectively with other related systems at national level (e.g. customs systems).[116]

The affected stakeholder groups are: competent authorities and economic operators along the supply chain, i.e. manufacturers, importers, distributors, wholesalers and retailer.[117]

5.2.2.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in this option is **highly probable**.

The affected stakeholder groups are: competent authorities and general public.[118]

5.2.3 Policy option 1b/2: One day time lag

5.2.3.1 Economic impacts

Economic costs

Manufacturers and importers[119]

CAPEX: EUR 2 million	OPEX: EUR 1 million	Annualised cost: EUR 1 million

During the consultations, most of the economic operators involved in tobacco trade expressed their preference for this option.

Distributors and wholesalers[120]

CAPEX: EUR 18 million	OPEX: EUR 12 million	Annualised cost: EUR 15 million

During the consultations, several stakeholders noted that daily uploads better reflect the current business practice geared to daily dispatches of goods. It was also suggested to have clear and timely requirements defining until when recording and transmitting have to take place instead of setting fixed-time intervals.

Economic benefits

The attainment of the reference level of benefits in the option of one day time lag reports is **less probable** as the technical evaluation has highlighted that it could cause potential delays in enforcement action.[121]

The attainment of the reference level of benefits could be more likely if this option is combined with additional requirements. During the consultations, it was suggested that the focus should be on when the shipment happens and not on the timing of pre-shipment

[116] See item 2-2 in section 7.4 of the Implementation Study, Annex 5.
[117] See Table 2.
[118] *Ibid.*
[119] See section 8.5.5 of the Implementation Study, Annex 6.
[120] *Ibid.*
[121] See item 6.1 in section 7.4 of the Implementation Study, Annex 6.

scans. Therefore, it was proposed to introduce an obligation to record any shipment of goods, i.e. movements between facilities, before the dispatch.

The affected stakeholder groups are the same as in option 1b/1. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[122]

5.2.3.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in the option of one day time lag reports is **less probable**.

The affected stakeholder groups are the same as in option 1b/1. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[123]

5.2.4 Policy option 1b/3: One week time lag

5.2.4.1 Economic impacts

Economic costs

Manufacturers and importers[124]

CAPEX: EUR 2 million	OPEX: EUR 1 million	Annualised cost: EUR 1 million

Even if the costs are estimated at the same level as in option 1b/2, during the consultations, many respondents disagreed with this option as creating far too long time lags in the recording and transmitting of data concerning the tracking and tracing events. Economic operators among others claimed that such a long time lag may lead to additional costs of data buffering and is not economically viable. No savings were expected as compared to the policy option of one day time lag.

Distributors and wholesalers[125]

CAPEX: EUR 18 million	OPEX: EUR 12 million	Annualised cost: EUR 15 million

The same comments as made above for manufacturers and importers are also relevant for distributors and wholesalers.

Economic benefits

The attainment of the reference level of benefits in the option of one week time lag reports may be **seriously compromised**.

According to Member States and many stakeholders, the recording and transmitting of data with such a long time lag defeats the objective of tracking and tracing.

The affected stakeholder groups are the same as in option 1b/1. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[126]

[122] See Table 2.
[123] *Ibid.*
[124] See section 8.5.5 of the Implementation Study, Annex 6.
[125] *Ibid.*
[126] See Table 2.

5.2.4.2 Social benefits

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in the option of one week time lag reports may be **seriously compromised**.

The affected stakeholder groups are the same as in option 1b/1. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[127]

5.3 Processing, storing and accessing data (Issue 1c)

5.3.1 Policy options for achieving objective 1c: 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

The cost benefit analysis of the policy options identified under objective 1c covers the establishment and operations of the data storage under the traceability system. Article 15(8) of the TPD requires that the data storage is provided by an independent third party contracted by manufacturers and importers. The third party's activities shall be monitored by an external auditor paid for by manufacturers. All these costs are fully attributable to manufacturers and importers. The external auditor will submit its annual report to the competent authorities and the Commission.

The policy options under objective 1c have also a direct impact on the Commission, which under Article 15(8) of the TPD is obliged to approve the suitability of the third party, the data storage contract and the external auditor.

5.3.2 Policy option 1c/1: Decentralised model as per manufacturer/importer

5.3.2.1 Economic impacts

Economic costs

Manufacturers and importers[128]

CAPEX: EUR 17 million	OPEX: EUR 5 million	Annualised cost: EUR 8 million

During the consultations, manufacturers largely favoured a decentralised model per manufacturer/importer, arguing that decentralisation per Member State (option 1c/2) would require complex levels of interoperability.

However, several smaller manufacturers favoured a centralised system which they said would simplify the data transmission process and be less burdensome. In this regard, the interests of distributors and wholesalers are aligned with those of smaller manufacturers.[129]

[127] *Ibid.*

[128] See section 8.3.5 of the Implementation Study, Annex 6.

[129] These concerns can be partially addressed by the inclusion of a central router as a part of Federation Services. It may also be advisable to include a most-favoured customer clause as an obligatory condition in the data storage contracts in order to protect small and medium manufacturers and importers.

Public authorities[130]

CAPEX: n/a	OPEX: EUR 2 million	Annualised cost: EUR 2 million

It is estimated that the Commission would be tasked with approving 230 data storage contracts and 7 auditors under this option.[131]

Economic benefits

The attainment of the reference level of benefits is **less probable**. It may be undermined in terms of the system's transparency and data quality. These problems among others translate into suboptimal surveillance capacity.

The technical evaluation shows that option 1c/1 has low efficiency with respect to read access. This option introduces: (a) a penalty on the reading performance, because the Federation Services have to forward each query to individual storages, wait for results and merge the collected data, (b) potential cross-storage compatibility problems, and (c) lower accessibility if not all individual storages function properly.[132] The "pure" distributed data storage system, i.e. without a central indexed copy of data, also impairs the ability of ensuring data integrity of the system as a whole, because the necessary data validation against the existing records needs to be handled via queries to remote systems.[133]

The affected stakeholder groups are: competent authorities and economic operators along the supply chain, i.e. manufacturers, importers, distributors, wholesalers and retailer. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[134]

5.3.2.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits is **less probable** than in option 1c/3.

The affected stakeholder groups are: competent authorities and general public. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[135]

[130] See section 8.3.5 of the Implementation Study, Annex 6.

[131] The number of data storage contracts is based on the number of tobacco enterprises indicated in the Feasibility Study, page 14. The number of auditors is based on Everis' assumption as to the number of data storage systems in options 1c/1 and 1c/3.

[132] This problem can be illustrated with a simple numerical example. If a single storage functions with 99% time availability (i.e. at any time there is a chance of 1 in 100 that a storage is down), a distributed system of seven storages will have only 93% time availability (because 0.99 to the power of 7 equals 0.93).

[133] See items 1-1 and 4-2 in section 7.2 of the Implementation Study, Annex 5.

[134] See Table 2.

[135] *Ibid.*

5.3.3 Policy option 1c/2: Decentralised model as per Member State

5.3.3.1 Economic impacts

Economic costs

Manufacturers and importers[136]

CAPEX: EUR 45 million	OPEX: EUR 12 million	Annualised cost: EUR 19 million

The relatively high cost of this option is due to a multiplication of processes at national level where the same implementation operations have to be carried out multiple times.

During the consultations, the health NGOs favoured a decentralised system per Member State, arguing that this would ease cross border investigation efforts, provided that a centralised surveillance element is also in place.

The technical evaluation shows that the decentralised option per Member State could pose problems for importers in the transmitting of data to correct data storage. This option represents the most complicated logic for routing reports.[137]

The option may also disproportionately impact small and medium-sized manufacturers and importers selling via distributors to several Member States, as such companies would most likely be obliged to enter into multiple contracts with storage providers from other Member States.

Public authorities[138]

CAPEX: n/a	OPEX: EUR 4 million	Annualised cost: EUR 4 million

It is estimated that the Commission would be tasked with approving 1490 data storage contracts and 19 auditors under this option.[139]

Economic benefits

The attainment of the reference level of benefits is **less probable**. It may be undermined by lower effectiveness of this option in terms of the system's transparency and data quality.[140] These problems among others translate into suboptimal surveillance capacity, in particular in the trans-border context.

The same problems with read access and data integrity are relevant as in option 1c/1.

The affected stakeholder groups are the same as in option 1c/1. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[141]

5.3.3.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits is **less probable** than in option 1c/3.

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[136] See section 8.3.5 of the Implementation Study, Annex 6.

[137] See item 1-2 in section 7.4 of the Implementation Study, Annex 5.

[138] See section 8.3.5 of the Implementation Study, Annex 6.

[139] The number of auditors is based on Everis' assumption as to the number of data storage systems in option 2a/2. The number of data storage contracts is based on the assumption that out of 230 concerned companies (see the Feasibility Study, page 14), 30 companies will sign contracts with all 19 data storage operators, 60 with 9, another 60 with 5 and last 80 with 1 (30 x 19 + 60 x 9 + 60 x 5 + 80 x 1 = 1490).

[140] See item 6-1 in section 7.4 of the Implementation Study, Annex 5.

[141] See Table 2.

The affected stakeholder groups are the same as in option 1c/1. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[142]

5.3.4 Policy option 1c/3: Combined model

5.3.4.1 Economic impacts

Economic costs

Manufacturers and importers[143]

CAPEX: EUR 19 million	OPEX: EUR 6 million	Annualised cost: EUR 9 million

The slight increase in costs for this option, as compared to option 1c/1, is due to the inclusion of a central copy of all data commonly accessible by all competent authorities (stored by an independent third party).

The technical analysis indicates that the existence of a central copy of data poses certain challenges in terms of data security and this part of the system will have to be adequately secured from cyber-attacks.[144] This being said, the data stored in the tobacco traceability system can be only potentially sensitive towards direct competitors, suppliers and clients, who have already a good overview of the market trends given the stable nature of demand.[145]

Competent authorities[146]

CAPEX: n/a	OPEX: EUR 2 million	Annualised cost: EUR 2 million

It is estimated that the Commission would be tasked with approving 230 data storage contracts and 7 auditors.

Economic benefits

The attainment of the reference level of benefits in the combined is **highly probable**.

Thanks to a central indexed copy of the data, this option ensures high performance and greater efficiency with respect to read access. It permits effective execution of more complex queries providing access to cross-sets of data and thereby enhancing overall transparency, which is key to attaining the objective of ensuring effective surveillance and monitoring. It also ensures high level of data integrity by providing for efficient data validation.[147] Last but not least, it will considerably facilitate the fulfilment of the international obligations by allowing for timely and effective responding to the requests received from the 'global information-sharing focal point' foreseen under Article 8 of the FCTC Protocol.

This option was considered by several Member States to be the best solution that will among others provide for effective surveillance and help in detecting duplicates. During the consultations, the following points were underlined as important for surveillance: (a) the

[142] *Ibid.*
[143] See section 8.3.5 of the Implementation Study, Annex 6.
[144] See item 5-1 in section 7.2 of the Implementation Study, Annex 5.
[145] There are commercially available information sources providing standardised and cross-comparable statistics including total market sizes, market share and brand share data, distribution and industry trends and sub-category level information. For example, see: http://www.euromonitor.com/tobacco.
[146] See section 8.3.5 of the Implementation Study, Annex 6.
[147] See items 1-1 and 4-2 in section 7.2 of the Implementation Study, Annex 5.

effectiveness of the query function, (b) the speed and ease of access, (c) the security of the data and recovery process, (d) the effectiveness of any interrogation, extraction and trend analysis functions and (e) the ability to modify any reporting tools. The technical evaluation indicates that points (a), (b), (d) and (e) can be fully addressed only under this option.[148]

The affected stakeholder groups are the same as in option 1c/1.

5.3.4.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in the combined is **highly probable**.

The affected stakeholder groups are the same as in option 1c/1.

5.4 Compatibility of components of the traceability system (Issue 2)

5.4.1 Policy options for achieving objective 2: To ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers

The cost benefit analysis of the policy options identified under objective 2 covers the following tasks:

- application of UIs (encoded in a data carrier (e.g. barcode)) to unit packets and higher aggregation levels;
- verification if UIs have been correctly applied.

Since the same tasks are also covered under objective 1a, the analysis under objective 2 takes into account only additional costs as compared to the costs already included under objective 1a. Some of the below options also lead to reductions in certain cost items included under objective 1a, such instances are clearly indicated.

In all policy options, the affected stakeholders are economic operators obliged to report the movements of tobacco products, notably (a) manufacturers and importers and (b) distributors and wholesalers. The latter group also includes vans used to service vending machines and mobile salesforce units. The CAPEX element of the costs incurred by distributors and wholesalers will be transferable to manufacturers under Article 15(7) of the TPD.

5.4.2 Policy option 2/1: Single data carrier per level

5.4.2.1 Economic impacts

Economic costs

Manufacturers and importers[149]

CAPEX: n/a	OPEX: n/a	Annualised cost: n/a

Under policy option 2/1, there are no additional costs to be incurred by manufacturers and importers as compared to the costs to be covered under the options presented under objective 1a.

[148] See items 1-1 and 6-1 in section 7.2 of the Implementation Study, Annex 5.
[149] See section 8.4.5 of the Implementation Study, Annex 6.

During the consultations, it was claimed that a system with a single data carrier would be too restrictive as well as detrimental for SMEs. Manufacturers stressed that prescribing a single data carrier would not facilitate operations and might lead to additional problems, such as in the case of imports/exports of products from/to third countries which may select different carriers. A number of stakeholders came up with recommendations of one to two optimal data carriers for each of packaging levels. These recommendations referred to several barcodes based on open standards, which are already in use in the sector. Open standards were viewed as means to allow maximum flexibility and interoperability.

Option 2/1 accommodates these stakeholder preferences, thanks to the possibility of adding optional (non-obligatory) data carriers. However, this option may pose problems if a mandatory data carrier pre-selected for a given packaging level does not meet the requirements of an important sub-type of packaging at that level.

Distributors and wholesalers[150]

CAPEX: EUR 151 million	OPEX: EUR 10 million	Annualised cost: EUR 35 million

The recommendations mentioned above for manufacturers and importers took into account the needs of distributors and wholesalers. This option is considered largely compatible with the requirements of the distribution chain.

Economic benefits

The attainment of the reference level of benefits in this option is **highly probable**.

Neither the consultation nor the technical evaluation suggests that option 2/1 poses any evident risks to attainment of the reference level of benefits.

The affected stakeholder groups are: competent authorities and economic operators along the supply chain, i.e. manufacturers, importers, distributors, wholesalers and retailers.[151]

5.4.2.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in this option is **highly probable**.

The affected stakeholder groups are: competent authorities and general public.[152]

5.4.3 Policy option 2/2: Limited variety of data carriers per level

5.4.3.1 Economic impacts

Economic costs

Manufacturers and importers[153]

CAPEX (reduction): EUR 12 million	OPEX: n/a	Annualised cost (reduction): EUR 2 million

Under policy option 2/2, manufacturers and importers are expected to lower the direct costs incurred under objective 1a, thanks to the broadening of a variety of permitted data carriers and hence potentially better reliance on the installed base of equipment.

[150] See section 8.4.5 of the Implementation Study, Annex 6.
[151] See Table 2.
[152] See Table 2.
[153] See section 8.4.5 of the Implementation Study, Annex 6.

The concept of a limited number of data carriers was largely favoured by stakeholders. The flexibility offered by this option was also recognised as addressing the needs of SMEs.

The technical evaluation further found that in comparison to option 2/1, option 2/2 enables economic operators to a larger extent to adapt the data carrier to the unit packet. In return, this means there is also a lower impact on the operation processes of manufacturers (facilitating ease of operation) as it would be the case in option 2/1.[154]

The same recommendations as mentioned in option 2/1 are applicable to option 2/2.

Distributors and wholesalers[155]

CAPEX: EUR 180 million	OPEX: EUR 10 million	Annualised cost: EUR 40 million

The support for this option by manufactures and importers expressed during the consultations was also mirrored by distributors and wholesalers. This option is considered compatible with the requirements of the distribution chain.

Economic benefits

The attainment of the reference level of benefits in this option is **highly probable**.

Neither the consultation nor the technical evaluation suggests that option 2/2 poses any evident risks to attainment of the reference level of benefits.

The technical evaluation further remarks that, as an unintended positive consequence, the implementation of this option, opposed to option 2/1, has the potential of promoting market competition. In return, this can drive innovation in the area of data carriers.[156]

The affected stakeholder groups are the same as in option 2/1.

5.4.3.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in this option is **highly probable**.

The affected stakeholder groups are the same as in option 2/1.

5.4.4 Policy option 2/3: Free system allowing any existing data carrier

5.4.4.1 Economic impacts

Economic costs

Manufacturers and importers[157]

CAPEX (reduction): EUR 25 million	OPEX: n/a	Annualised cost (reduction): EUR 4 million

Under policy option 2/3, manufacturers and importers are expected to lower their direct costs included under objective 1a thanks to the lack of any restrictions as to the choice of data carriers by individual operators and hence potentially high reliance on the installed base of equipment.

[154] See item 1-1 and 1-3 in section 7.3 of the Implementation Study, Annex 5.
[155] See section 8.4.5 of the Implementation Study, Annex 6.
[156] See item 7-3 in section 7.3 of the Implementation Study, Annex 5.
[157] See section 8.4.5 of the Implementation Study, Annex 6.

However, during the consultations, most of stakeholders expressed doubts as to this option. Stakeholders were particularly concerned that this option would lead to incompatibility of the readers at the industry's disposal.

In the technical evaluation, option 2/3, although allowing for more flexibility in adapting to the production process[158], is considered suboptimal in terms of the system's overall consistency.[159]

Distributors and wholesalers[160]

CAPEX: EUR 239 million	OPEX: EUR 10 million	Annualised cost: EUR 49 million

The same risks related to this option raised for manufacturers and importers are equally applicable to distributors and wholesalers.

Economic benefits

The attainment of the reference level of benefits in option 2/3 is **less probable**.

During the consultations, it was stressed that this option could lead to the unawareness of competent authorities concerning certain data carriers in use and therefore could undermine their control functions.

The affected stakeholder groups are the same as in option 2/1. The economic benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[161]

Furthermore, the technical evaluation remarks that, as an unintended positive consequence, the implementation of this option, opposed to option 2/1, has the potential of promoting market competition. In return, this can drive innovation and consequently result in a drop in market prices for the data carriers at question.[162]

5.4.4.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in option 2/3 is **less probable**.

The affected stakeholder groups are the same as in option 2/1. The social benefits for each stakeholder group should be adjusted downwards in a proportionate manner to their share in the reference level of benefits.[163]

5.5 Security feature

5.5.1 Policy options for achieving objective 3: to facilitate the authentication of tobacco products by an optimal selection of application methods for security features

The cost benefit analysis of the policy options identified under objective 3 is incremental from the perspective of competent authorities, i.e. it is based on the existing tax stamp programmes of Member States. It includes only approximate costs of likely adaptations by

[158] See item 1-1 and 1-3 in section 7.3 of the Implementation Study, Annex 5.
[159] See item 4-1 in section 7.3 of the Implementation Study, Annex 5.
[160] See section 8.4.5 of the Implementation Study, Annex 6.
[161] See Table 2.
[162] See item 7-3 in section 7.3 of the Implementation Study, Annex 5.
[163] See Table 2.

Member States to the requirements introduced with Article 16 of the TPD, where the existing tax stamp programmes serve as a starting point.

The affected groups of stakeholders are: (a) manufacturers and importers who are assumed to cover the costs of security features and (b) competent authorities who will need to oversee the process.

The cost analysis relies on the survey of Member States carried out by the external contractor providing input to the Commission. This survey led to the following broad assumptions:

- 84% of all products are presently secured with tax stamps, where:
    - 66% of all products are secured with tax stamps not requiring updates;
    - 18% of all products are secured with tax stamps requiring updates;
- 16% of all products are presently not secured with tax stamps.[164]

5.5.2 Policy option 3/1: Printing or affixing

5.5.2.1 Economic impacts per stakeholder group

Economic costs

Manufacturers and importers[165]

CAPEX: n/a	OPEX: EUR 15 million	Annualised cost: EUR 15 million

The cost calculations are based on the unit costs of tax stamps and printed security features reported in the Feasibility Study and the assumption that 34% of all products will be affected by the new rules.

During the consultations, manufacturers agreed that building on existing practices (such as tax stamps) is a good approach but also stressed that it is essential to retain flexibility and innovation so as to limit the possibility of counterfeiting.

Competent authorities

The estimates do not include specific costs for competent authorities. It is assumed that the competent authorities will shift the economic burden to manufactures and importers. Therefore, the inclusion of separate costs would lead to double counting.

During the consultations, some Member States explained that tax stamps were not used in their country and therefore any solution being solely based on tax stamps would not be supported. Other Member States, on the contrary, were strongly in favour of continued use of tax stamps. In this regard, it must be recalled that not all tax stamps currently used may meet the requirements under the TPD regime, including technical specifications to be introduced in the implementing act.

Economic benefits

The attainment of the reference level of benefits in this option is **highly probable**.

Option 3/1 poses no evident risks to attainment of the reference level of benefits. Its strength is that it makes the harmonisation of rules concerning application methods

[164] See section 8.6.1 of the Implementation Study, Annex 6.
[165] See section 8.6.4 of the Implementation Study, Annex 6.

relatively easier, given the assumption that the choice of application methods does not include a combination of all methods.

The affected stakeholder groups are: competent authorities and economic operators along the supply chain, i.e. manufacturers, importers, distributors, wholesalers and retailers.[166]

5.5.2.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in this option is **highly probable**.

The affected stakeholder groups are: competent authorities and general public.[167]

5.5.3 Policy option 3/2: Printing or affixing or a combination of printing and affixing

5.5.3.1 Economic impacts

Economic costs

Manufacturers and importers

CAPEX: n/a	OPEX: EUR 15 million	Annualised cost: EUR 15 million

The broad cost estimates for option 3/2 do not differ from option 3/1. However, option 3/2 introduces an additional degree of freedom by allowing for a combination of different application methods. With respect to 18% of all products, there will be a possibility of introducing the TPD security feature with a potentially more cost effective method, which under this option might be a combination of the existing tax stamp with other additional elements applied directly on the pack. The technical evaluation further notes that a higher degree of flexibility in the available application method makes it easier to adapt to the differences in product material and packaging.[168] Therefore, this option also better reflects the interests of SMEs that insisted on flexibility and broad choice as important factors for them.

Competent authorities

During the consultations, it was argued that Member State should be allowed to choose the most appropriate system and it should be technically feasible for all products and producers and must allow for easy authentication by enforcers. A multi-layered system on different parts of the pack was suggested.

Economic benefits

The attainment of the reference level of benefits in this option is **highly probable**.

Option 3/2 poses no evident risks to attainment of the reference level of benefits. Its particular strength is higher adaptability, which should better address the varied risks of counterfeiting.

The affected stakeholder groups are the same as in option 3/1

[166] See Table 2.
[167] See Table 2.
[168] See item 6-2 in Section 7.5 of the Implementation Study, Annex 5.

5.5.3.2 Social impacts

For the same reasons as indicated in the above section on economic benefits, the attainment of the reference level of social benefits in this option is **highly probable**.

The affected stakeholder groups are the same as in option 3/1

6 COMPARING THE OPTIONS

The policy options presented above are compared against the criteria of effectiveness (i.e. to what extent they fulfil the objectives identified in section 3 and allow for preventing and discovering potential fraud cases resulting in illicit trade) and efficiency (i.e. at what cost they do so). Particular attention is given to specific impacts of individual options on SMEs. The preferred options should take into account the need for minimalizing impacts on SMEs as far as possible within the general objective of establishing the systems of traceability and security features for tobacco products.

In the case of trade-offs between effectiveness and efficiency, due regard is given to the fact that the estimated benefits[169] largely outweigh (more than twenty times) the estimated costs.[170]

6.1 Marking packages with a unique identifier (Issue 1a)

Comparison of options for objective 1a: 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		
POLICY OPTIONS	EFFECTIVENESS	EFFICIENCY
1a/1: Industry operated solution	MEDIUM – given the existing economic incentives for misusing the traceability system by economic operators and their employees.	LOW to MEDIUM – the annualised costs are estimated at EUR 55.2 million. It also calls for considerable effort on the part of competent authorities with quasi-permanent controls of the industry facilities.
1a/2: Third party operated solution	HIGH – the system is better protected from potential misuse due to the involvement of an independent service provider.	MEDIUM – the annualised costs are estimated at EUR 44.1 million. The involvement of an independent service provider in operating the production hardware may lead to liability issues and negatively impact the tobacco manufacturing processes and consequently their costs.
1a/3: Mixed solution (industry and third party)	HIGH – the system is better protected from potential misuse due to the involvement of an independent service provider with respect to key functions.	MEDIUM to HIGH – the annualised costs are estimated at EUR 43 million. The involvement of an independent service provider is limited to the functions relevant for the system's overall integrity (i.e. generation of key parts of UIs and control over verification of UIs) and hence the risks of liability issues and negative impacts on the tobacco manufacturing processes are mitigated.

[169] See Table 2.
[170] See sections 5.1 – 5.5 and Table 3.

SMEs specific impacts for objective 1a: 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		
Policy options	Impacts 1- minimum 2- medium 3- high	Comments
1a/1: Industry operated solution	2	SMEs may not have all competences to operate all tasks, in particular generation of UIs may be problematic.
1a/2: Third party operated solution	3	Presence of third party on the production lines may have a disproportionally high impact on SMEs.
1a/3: Mixed solution (industry and third party)	1	SMEs will be able to benefit from economies of scale created with the external generation of key parts of UIs.

Option 1a/3 provides for the best combination of effectiveness and efficiency and is the most proportionate option. It allows for the full attainment of objective 1a – independence of the system, keeping the potentially disruptive involvement of a third party in the tobacco manufacturing processes to the necessary minimum. Option 1a/3 ensures compliance with the FCTC Protocol by providing authorities with full control over key functions of the system, in particular with respect to the generation of UIs. This option also minimises the costs and hence has no excessive effect on economic operators. Finally, this option has minimised impacts on SMEs and high technical feasibility.

In sum, this option provides the most balanced approach considering the highly differentiated nature of concerns raised by stakeholders representing divergent interests.

6.2 Recording and transmitting data (Issue 1b)

Comparison of options for objective 1b: 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		
POLICY OPTIONS	EFFECTIVENESS	EFFICIENCY
1b/1: Near real time reports	HIGH – high visibility of events and accurate information in the system, allowing for immediate corrective actions.	MEDIUM – the annualised costs are estimated at EUR 48.7 million. It is already practiced by big manufacturers, but as it is not current business practice overall, it will be very demanding for SMEs to implement in time.
1b/2: One day time lag	MEDIUM – it creates a limited period (up to a day) of blindness in the system impacting negatively on the accuracy of information.	HIGH – the annualised costs are estimated at EUR 15.9 million. It is in line with the current business practice. It is not problematic in terms of technical roll-out.
1b/3: One week time lag	LOW – it creates a long period of blindness, i.e. impairs the accuracy of data and hence defeats the objective of the tracking and tracing system.	MEDIUM to HIGH – the annualised costs are estimated at EUR 15.9 million. However the costs may be higher due to a too long time lag in the transmitting of data and the related costs of local buffering of data.

SMEs specific impacts for objective 1b: 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		
Policy options	Impacts 1- minimum 2- medium 3- high	Comments
1b/1: Near real time	3	Potentially heavy burden as SMEs mainly operate with

		manual processes.
1b/2: One day time lag	1	In line with the current business practice.
1b/3: One week time lag	2	This option may require an IT investment in local data storage.

Option 1b/1 provides for the best combination of effectiveness and efficiency in the long run. However, this option may be difficult to technically implement in the short term, in particular for SMEs. Therefore, the system may need to be initially based on option 1b/2, while option 1b/1 would be gradually introduced. A necessary transition period may vary for small and big operators. In order to improve the effectiveness of option 1b/2, it will have to be combined with strict rules as to the recording and transmission of data concerning the dispatching events prior to the actual shipment.

Overall, in the long run option 1b/1 is necessary to attain the full accuracy of surveillance information and therefore the possibility of immediate incident detection. The additional annualised cost of almost EUR 33 million to be incurred in option 1b/1, as compared to option 1b/2, is considered to be proportionate given the significant level of expected social and economic benefits.[171] The latter may not be fully attainable under option 1b/2.

6.3 Processing, storing and accessing data (Issue 1c)

Comparison of options for objective 1c: 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		
POLICY OPTIONS	EFFECTIVENESS	EFFICIENCY
1c/1: Decentralised model as per manufacturer / importer	LOW – the system may not be fully transparent, the quality of data may be compromised and the ability of competent authorities to access the full set of data may be negatively impacted.	HIGH – the annualised costs are estimated at EUR 9.3 million. It provides flexibility to both bigger and smaller operators in selecting data storage providers.
1c/2: Decentralised model as per Member State	LOW – the system may not be fully transparent, the quality of data may be compromised and the ability of competent authorities (of other Member States) to access the full set of data may be negatively impacted.	MEDIUM – the annualised costs are estimated at EUR 23.5 million. It represents the most complicated routing logic and may be challenging in terms of interoperability. It also requires a much higher administrative effort in dealing with high number of data storage contracts.
1c/3: Combined model	HIGH – the high performance and transparency of the system is ensures through a central copy of data facilitating access to the full set of data.	HIGH – the annualised costs are estimated at EUR 10.5 million. It provides flexibility to both bigger and smaller operators in selecting data storage providers. It includes a central copy of data. It will also lower administrative burden of dealing with enquiries to and from the future global information sharing point under the FCTC Protocol.

SMEs specific impacts for objective 1c: 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		
Policy options	Impacts 1- minimum 2- medium	Comments

[171] See Table 2.

	3- high	
1c/1: Decentralised model as per manufacturer / importer	1	For SMEs active in manufacturing and importing there is a need to sign only one contract for data storage.
1c/2: Decentralised model as per Member State	3	For SMEs active in manufacturing and importing there is a need to sign multiple contracts for data storage.
1c/3: Combined model	1	For SMEs active in manufacturing and importing there is a need to sign only one contract for data storage.

Option 1c/3 provides for the best combination of effectiveness and efficiency. This option is necessary for achieving effective monitoring and enforcement by authorities. Other options do not guarantee this to the extent required. The additional annualised cost of around EUR 1 million incurred in option 1c/3, as compared to the least expensive option 1c/1, is considered to be proportionate given the significant level of expected social and economic benefits.[172] The same results would not be attained under option 1c/1. Furthermore, option 1c/3 minimises the impacts on SMEs.

Option 1c/3 creates the maximum EU added value by facilitating Member States' surveillance of goods in transit or those that originate from another Member State. In particular, Member States will be able to access a full data set relating to any product recorded in the system without undue delays. This possibility will also enable competent authorities to more easily identify suspicious cross-border activities (e.g. attempted recording of the same UIs in two or more Member States).

Finally, as option 1c/3 will ensure that a copy of all information recorded under the EU's traceability system is stored in one location, it is likely to greatly facilitate enquiries to and from the future global information sharing point, as specifically required under Article 8(8) of the FCTC Protocol. It is therefore the policy option most likely to contribute to achieving the specific objective of international interoperability.

6.4 Compatibility of components of the traceability system (Issue 2)

Comparison of options for objective 2: To ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers		
POLICY OPTIONS	EFFECTIVENESS	EFFICIENCY
2/1: Single data carrier per level	HIGH – the system will be interoperable and transfer of data is facilitated.	HIGH – the annualised costs are estimated at EUR 34.8 million. It offers a certain degree of freedom based on a predefined data carrier per each packaging level.
2/2: Limited data carriers per level	HIGH – the system will be interoperable and transfer of data is facilitated.	HIGH – the annualised costs are estimated at EUR 37.6 million. It offers a high degree of freedom on the basis of a pre-selected set of permitted data carriers. This option will best accommodate the needs of SMEs.
2/3: Free system allowing any existing data carrier	LOW – in case of the unawareness of economic operators or competent authorities concerning certain data carrier(s) in use, it may seriously undermine the system's interoperability and negatively impact transfer of data.	MEDIUM – the annualised costs are estimated at EUR 45.4 million. Unstructured approach to data carriers will result in additional costs of adapting to a too broad range of data carriers and dealing with potentially less known solutions.

[172] *Ibid.*

SMEs specific impacts for objective 2: To ensure an effective transfer of information throughout the distribution chain by an optimal selection of data carriers		
Policy options	Impacts 1- minimum 2- medium 3- high	Comments
2/1: Single data carrier per level	2	Medium level of flexibility that should enable SMEs to mitigate their installation/equipment costs
2/2: Limited data carriers per level	1	High level of flexibility that should enable SMEs to minimise their installation/equipment costs
2/3: Free system allowing any existing data carrier	3	It meets the requirements of SMEs active in manufacturing, but at the same time it represents a need for constant adaptations on the part of SMEs active in distribution.

Option 2/3 is the least favourable option, while options 2/1 and 2/2 are close in terms of effectiveness and efficiency. However, **option 2/2** provides for a higher degree of freedom for economic operators and is therefore considered to be the preferred option. Due to a higher degree of flexibility in adapting to the production process, option 2/2 further provides for minimised impacts on SMEs, which under option 2/1 would be exposed to potentially higher installation and equipment costs. In comparison to option 2/1, option 2/2 may also come with the unintended positive consequence of promoting market competition, which would likely drive innovation in the area of data carriers. Option 2/2 also avoids potential technical problems if a mandatory data carrier pre-selected for a given packaging level under option 2/1 does not meet the requirements of an important sub-type of packaging at that level. Against the foregoing, the additional annualised cost of around EUR 3 million incurred in option 2/2, as compared to the least expensive option 2/1, is considered to be proportionate.

6.5 Security features (Issue 3)

Comparison of options for objective 3: to facilitate the authentication of tobacco products by an optimal selection of application methods for security features		
POLICY OPTIONS	EFFECTIVENESS	EFFICIENCY
3/1: Printing or affixing	HIGH – it offers higher potential for harmonisation at the expense of lower adaptability to various security risks.	MEDIUM to HIGH – the annualised costs are estimated at EUR 14.9 million.
3/2: Printing or affixing or a combination of printing and affixing	HIGH – it offers slightly lower potential for harmonisation at the benefit of higher adaptability to various security risks.	HIGH – the annualised costs are estimated at EUR 14.9 million. However, a higher level of efficiency is achieved due to increased flexibility as compared to option 3/1, which may lead to lower costs for economic operators.

SMEs specific impacts for objective 3: to facilitate the authentication of tobacco products by an optimal selection of application methods for security features		
Policy options	Impacts 1- minimum 2- medium 3- high	Comments
3/1: Printing or affixing	2	Medium level of flexibility, which may affect SMEs' ability to acquire security features at the lowest cost.
3/2: Printing or affixing or a combination of printing and affixing	1	High level of flexibility allowing SMEs for acquiring security features at the lowest cost and better adapting to the differences in product material and packaging.

Option 3/2 provides for the best combination of effectiveness and efficiency and is the most proportionate option. It results in a higher degree of efficiency, due to increased flexibility, and hence may lead to lower economic costs for economic operators. As such, this option also minimises impacts on SMEs.

6.6 Summary of preferred options

In conclusion, the optimal set of policy options for this initiative is found to consist of:

- Option 1a/3 – adopting the mixed model of governance for the tracking and tracing system;
- Option 1b/1 – requiring the economic operators involved in tobacco trade to report in near real time (this requirement will be subject to a transition period and more lenient approach to SMEs);
- Option 1c/3 – adopting the combined model of data storage with individual data storages per manufacturer/importer and the central surveillance system including a central copy of data;
- Option 2/2 – introducing a limited variety of mandatory data carriers, where at least one of them has to be used;
- Option 3/2 – permitting that the security feature can be added to the unit pack by printing or affixing or a combination of printing and affixing.

The preferred options are expected to deliver reference level of social and economic impacts as set out in Table 2. Moreover, it should be noted that in particular the combination of options 1b/1 (near real time reports) and 1c/3 (combined model of data storage) are expected to provide for timely and efficient access to the traceability data for competent authorities.

The cost implications of the preferred options are summarised in Table 4 below. In addition, the impacts are also shown in terms of the estimated cost per unit pack.

Preferred policy options	Annualised cost (EUR million)	Cost per unit pack (EUR)
1a/3: Mixed solution (industry and third party)	43.0	0.001451
1b/1: Near real time reports	48.7	0.001642
1c/3: Combined model	10.5	0.000353
2/2: Limited data carriers per level	37.6	0.001268
Total (Article 15 TPD)	139.7	0.004714
3/2: Printing or affixing or a combination of printing and affixing	14.9	0.000502
Total (Articles 15 & 16 TPD)	154.6	

Table 4: *Overall cost implications*

In total, the annualised costs of the present initiative are estimated at EUR 155 million, including EUR 140 million for the traceability system. The overall costs compare very favourably to the expected annual social and economic benefits of EUR 3.8 billion (see Table 2), even if the achievement of the full benefits should not be expected immediately after the launch of the system.[173] The costs amount to a small fraction of the estimated benefits. The sensitivity checks show that even if the expected costs of the system were

[173] The Implementation Study tested the sensitivity of its cost-benefit analysis and in all scenarios the initiative shows a high positive internal rate of return (IRR).

increased by a factor of 2 or 3 and the benefits were halved, the overall outcome would be still positive and the expected additional costs per tobacco unit packet would remain minimal. It should be also noted that in terms of legal revenues, the system is expected to partially finance itself, given that it will generate EUR 59 million in the increased profits for legal economic operators.

The costs can be further split among the affected stakeholder groups. It is assumed that the economic operators will incur the bulk of the costs. The costs of the economic operators are estimated at EUR 151 million. The competent authorities are expected to cover the remaining amount of EUR 4 million.[174] Table 5 below shows the distribution of both annual costs and benefits among the affected stakeholder groups.

Affected stakeholders	Social benefits	Economic benefits	Economic costs
Competent authorities	219	2029	4.1
Economic operators, incl.: - manufacturers/importers - distributors/wholesalers - retailers	n/a	59.1 45.4 5.8 7.9	150.6 78.9 71.6 n/a
General public	1497	n/a	n/a
Total	1716	2088	155

Table 5: *Annual costs and benefits per stakeholder group (in EUR million)*

The unit cost of the traceability system is below half a eurocent. It is unlikely to translate into any meaningful increase of the prices of the tobacco products manufactured in the EU. Therefore, the costs of this initiative are not expected to have any negative impact on international trade[175] and the competitiveness of the EU tobacco industry.[176]

Given the very low unit costs of traceability and security features (even after addition of taxes and excise duties) [177], the initiative is also unlikely to affect the existing consumers of legal products. Even if niche producers who may incur a higher increase in costs per unit decide to carry over these costs to the consumers, it will only increase the social and economic benefits given the fact that the value added of the tobacco industry is lower than the sum of the social and economic costs of tobacco consumption.[178]

[174] The costs for the competent authorities are assumed to be spread out among all Member States. However, the competent authorities of the countries of manufacturing are expected to incur proportionally higher costs.

[175] It is recalled that the impact on trade was already analysed in the TPD Impact Assessment.

[176] The costs of aligning the security features with the TPD have no impact on the international competitiveness of the EU tobacco industry, because the requirement of applying a security feature applies equally to EU and non-EU products destined for the EU markets.

[177] Average post-tax unit price is estimated at EUR 4.38.

[178] See Annex 5 of TPD Impact Assessment.

7 MONITORING AND EVALUATION

Within the currently valid legislation, several elements of monitoring and evaluation are foreseen:

Under Article 28 of the TPD the Commission is required to submit a report to the European Parliament and to the Council no later than five years from 20 May 2016. This report shall focus on the application of the Directive's main provisions. The Commission intends to consult with Member States during its preparation and they will in turn be requested to provide all relevant available information.

As the systems of traceability and security features provided for under Articles 15 and 16 of the TPD will have become applicable to cigarettes and roll-your-own tobacco products by the time of submission of this report,[179] monitoring and evaluation of the application of these provisions will be included. Member States will be asked to share their experiences with the system, e.g. how many fraud investigations were supported with the intelligence delivered by the system.

In addition to the above-mentioned report, general monitoring of the traceability system will be facilitated through access to the data storage facilities for the Commission and national competent authorities as foreseen under Article 15(8) of the TPD. Via this access, it will be possible for authorities to gain an overview of compliance with the provisions of Article 15 across the supply chain and the functioning of the traceability system as a whole. Additionally, Article 15(8) sets out that an external auditor, proposed and paid for by the relevant tobacco manufacturer and approved by the Commission, shall submit an annual report to the competent authorities and the Commission relating to the data storage facility in question, assessing in particular any irregularities in relation to access to the data stored by that facility.

Furthermore certain indicators should be developed to evaluate the system's effectiveness over time, such as how often the system is consulted by the competent authorities or how often the system generates alerts pointing at potential irregularities, which may serve as proxies for the system's usefulness in fighting illicit trade. These should notably deliver insights into the achievement of the objectives and allow collection of quantified data and information on the state of implementation.

For the specific objectives (to ensure effective tracking and tracing for tobacco products within the EU; to ensure an effective system of security features for tobacco products), the following indicators could be employed:

- Data recorded and stored pursuant to Article 15;
- Data derived from legal sales and/or fiscal revenues;
- Comparison of data recorded and stored pursuant to Article 15 with data derived from legal sales and/or fiscal revenues from tobacco products.

For an evaluation of the wider context and the longer term impact of the systems, the following indicators could be used:

[179] The provisions of Article 15 and 16 of Directive 2014/40/EU shall apply to cigarettes and roll your own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

- Smoking prevalence rates in the EU, which could be assessed by surveys and market monitoring exercises, e.g. regular Eurobarometer surveys;[180]
- Public perceptions of illicit tobacco trade, assessed, for example, by Special Eurobarometer surveys;[181]
- Illicit tobacco market trends in the EU, assessed by data from commercial providers (e.g. Euromonitor).

On this basis, it will be possible for competent authorities and/or the Commission to map changing trends in tobacco product consumption. This will allow for the effect of the expected reduction in the availability of illicit tobacco products over time to be quantified. Such a quantification attempt may take the form of a natural event analysis on the cross-country panel data set, once the sufficient number of observations is collected. Subject to the existing limitations in studying illicit activities, the analysis may test the effectiveness of the system in combating the illicit trade in tobacco.

[180] Eurobarometer surveys have been carried out in the EU since 2003 to assess the attitudes of Europeans towards tobacco, including the prevalence of tobacco use, and to explore the motivations for smoking. The latest Eurobarometer (458) was based on the fieldwork carried out in March 2017: http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKy/79003.

[181] http://ec.europa.eu/anti-fraud/sites/antifraud/files/eurobarometer_report_illicit_tobacco_trade_en.pdf. This survey aimed to uncover and explore the attitudes and opinions of Europeans in regard illicit tobacco trade

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