

INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Implementing and delegated acts under Articles 15(11), 15(12) and 16(2) of the Tobacco Products Directive 2014/40/EU		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG SANTE – B2	DATE OF ROADMAP	5 July 2016
LIKELY TYPE OF INITIATIVE	<i>Commission Implementing Decision</i>		
INDICATIVE PLANNING	<i>4th quarter 2017</i>		
ADDITIONAL INFORMATION	-		
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A. Context, Subsidiarity Check and Objectives

Context
<p>Tobacco Products Directive</p> <p>The present initiative will implement Articles 15 and 16 of the Tobacco Products Directive (TPD) 2014/40/EU¹ by means of implementing and delegated acts as envisaged in Articles 15(11), 15(12) and 16(2) of the TPD.</p> <p>The TPD's overall objective 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 products², including traceability and security features as the measures intended to secure the supply chain. The TPD 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, and the obligations of the European Union (EU) under the Framework Convention for Tobacco Control (FCTC). Articles 15 and 16 of the TPD aim at fighting illicit trade in tobacco products and thus, from a public health perspective, contribute to reducing the artificially cheap supplies of illegal tobacco products that affect the uptake and general prevalence of smoking.</p> <p>Article 15 of the TPD requires that tobacco products can be tracked and traced. For this to be achieved it is required that all unit packets of tobacco products manufactured in or imported into the Union are marked with a unique identifier (containing defined data elements) and that their movements are recorded throughout the supply chain (up to the last level before retail). In addition to tracking and tracing, Article 16 of the TPD requires that all unit packets of tobacco products, which are placed on the EU market, carry a tamper proof security feature composed of visible and invisible elements.</p> <p>The above requirements 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.</p> <p>FCTC Protocol</p> <p>The FCTC is an international treaty negotiated under the auspices of the WHO. It was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. The EU signed the FCTC on 16 June 2003 and confirmed on 30 June 2005.</p> <p>The FCTC contains provisions concerning supply and demand reduction of tobacco products, including an Article on illicit trade. On that basis and in order to address the problem of illicit trade, a Protocol to Eliminate Illicit Trade in Tobacco Products (FCTC Protocol) was developed, negotiated by FCTC Parties, and finally adopted by the Conference of the Parties (COP) of the FCTC on 12 November 2012. The FCTC Protocol aims at eliminating illicit trade in tobacco products. It provides tools for preventing and combatting illicit trade by securing the supply chain, including by establishing an international tracking and tracing regime, by countering illicit trade through dissuasive law enforcement measures and a range of measures to strengthen international cooperation.</p>

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. 1-38.

² See Article 1 of the TPD.

On 4 May 2015, the Commission proposed that the Council concludes the Protocol on behalf of the EU. The decision to ratify should be adopted by the Council with the consent of the European Parliament.

Entry into force of Article 15 of the TPD as well as the forthcoming implementing legislation will make a key contribution to the effective implementation of the FCTC Protocol by the EU.

Broader policy context

Reducing illicit trade will contribute to reducing tobacco consumption and thus alleviate the burden on health budgets for Member States. In addition, as an important side effect, reducing illicit trade will increase budget revenues from the taxes on tobacco products³.

A recent study estimated the amount of duty that EU tax administrations lose to illicit trade at about €11.1 billion a year. The elimination of illicit trade was estimated to increase the tax revenues in the range of €6.1 billion to €7.2 billion a year⁴ (after discounting for decreases in the tobacco consumption of artificially cheaper illicit products according to price elasticity⁵).

The establishment of a tracking and tracing system, as the key measure to secure the supply chain, is also a part of the comprehensive EU strategy to step up the fight against cigarette smuggling and other forms of illicit trade in tobacco products.⁶ The strategy proposes measures around four areas. Apart from securing the supply chain, the proposed measures seek to decrease incentives, strengthen enforcement and strengthen sanctions. The measures are complementary and mutually reinforcing. The system will also support the implementation of the EU Strategy and Action Plan for customs risk management⁷. The systematic real-time availability and replicability of the data can support a more effective and efficient risk-based customs supervision approach for tobacco products coming from outside the EU.

Previous tobacco product measures

The TPD repealed Directive 2001/37/EC (the previous TPD), which contained under Article 5(9) the possibility to introduce provisions on traceability and product identification (batch numbering).

The adoption of the TPD was preceded by a comprehensive Impact Assessment.⁸ With regard to illicit trade, the provisions of Article 5(9) of Directive 2001/37/EC were considered insufficient as they did not provide for a fully-fledged traceability system. The batch marking envisaged by Article 5(9) is only one element for achieving traceability and control of the supply chain. It is insufficient to determine the origin and the point of diversion and to monitor, document, and control the movement of tobacco products and their legal status.

Agreements with the industry

The EU and all Member States have signed legally binding and enforceable anti-fraud Agreements with PMI (2004-2016) and JTI (2007-2022) and the EU and 26 Member States have signed Agreements with BAT and ITL (2010-2030). The Agreements include provisions on tracking and tracing. However, the Agreements do not provide for level playing field for all economic operators. Apart from the four tobacco manufactures, other manufacturers and importers do not have similar legal obligations to control the supply chain through tracking and tracing. Moreover, the scope of the tracking and tracing system used under the Agreements is substantially narrower in a number of important aspects, including the depth and breadth of tracking and tracing and the level of independent control (whilst being wider in other aspects).⁹

³ The relevant EU legislation consists of the Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco.

⁴ Study on the measuring and reducing of administrative costs for economic operators and tax authorities and obtaining in parallel a higher level of compliance and security in imposing excise duties on tobacco products (Ramboll Study), see: http://ec.europa.eu/taxation_customs/resources/documents/taxation/excise_duties/tobacco_products/studies_reports/rambo-ll-tobacco-study.pdf

⁵ 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.

⁶ 2013 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, COM(2013) 324 final.

⁷ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on *the EU Strategy and Action Plan for customs risk management: Tackling risks, strengthening supply chain security and facilitating trade*; COM (2014) 527 of 21st August 2014, endorsed by Council in December 2014.

⁸ See the TPD Impact Assessment at: http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf

⁹ At least for the time being, the industry's system does not systematically operate at the lowest aggregation level, i.e. packet level, does not cover the full distribution chain and last but not least, is operated without any real-time verification by a

Issue

Illicit trade

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

The implementation of Articles 15 and 16 of the TPD aims at increasing the security of the legal supply chain and hence safeguarding the TPD requirements, along with the reduction of the artificially cheap supplies of illicit products. This will contribute to the reduction of the prevalence of smoking, according to price elasticity.

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 deaths in the EU, responsible for almost 700,000 deaths every year.¹⁰

Size of the problem and its main drivers

The value of the EU tobacco products market, including VAT and excise taxes, is estimated at around EUR 130 billion, while the before-tax value is estimated at EUR 31 billion at the retail level and EUR 19 billion at the ex-factory prices.¹¹

Tobacco products are traded both internationally and within the EU. The officially declared, before-tax value of the intra EU trade (covering the main categories of tobacco products, but without roll-your-own tobacco) is around 8 billion (see Table 1), i.e. over 25% of the before-tax value of the retail market and between 40% and 50% of the ex-factory market.

Table 1: Intra EU-28 trade in cigars, cheroots, cigarillos and cigarettes of tobacco or of tobacco substitutes (before taxes, in mEUR)

2010	2011	2012	2013	2014
8,293	8,862	8,671	7,710	7,487

Source: Eurostat (Comext data code: DS-016894)

In the context of the present initiative, it is important to note that the after-tax prices of tobacco products considerably differ among Member States (see Table 2). This creates incentives for the intra EU illicit trade in the tobacco products already taxed in one Member State and subsequently illegally moved to, and clandestinely sold in another Member State with higher after-tax prices.

Table 2: Differences in Weighted Average Prices (WAC) across Member States (after taxes, in EUR, in 2012)

Average EU price per pack of 20 cigarettes	4.15
Max EU price per pack of 20 cigarettes	9.32
Min EU price per pack of 20 cigarettes	2.30

Source: Ramboll Study

There are also considerable differences between the EU and third countries in terms of after-tax prices. In the countries bordering with the EU, the after-tax weighted average price (WAC) can be as low as EUR 0.60 per pack of 20 cigarettes.¹² Access to cheap products on the legal markets of the third countries in addition to the

third party. An advantage of the industry's system is its coverage of non-EU production of tobacco products, which may be redirected to the EU markets. This advantage will diminish along with the successive accession of non-EU countries to the FCTC Protocol as it will expand the coverage of industry independent tracking and tracing to those countries.

¹⁰ The TPD Impact Assessment, p. 1-2 and 15.

¹¹ Matrix Study, page 167. See: http://ec.europa.eu/health/tobacco/docs/tobacco_matrix_report_eu_market_en.pdf

¹² Project SUN, 2014 results, p. 9. See: http://kpmg.co.uk/creategraphics/2015/06_2015/CRT026736/index.html

clandestine manufacturing provide for part of the supplies of products being subsequently smuggled into the EU territory. The reflection of such activities can be found in the customs seizure statistics. For example, the total volume of seized cigarettes in the EU accounted for 3.1 billion sticks in 2013.¹³

The price differences combined with the illegal manufacturing of tobacco products lead together to substantial illicit trade, which undermines the effectiveness of the TPD provisions and the overall health objectives of the tobacco control policy. For example, it is estimated that the illicit trade accounts for around 13% of the total consumption of cigarettes in the EU (see Table 3). However, due to its clandestine and multi-facet nature, the precise size of illicit trade remains unknown and can be at best only approximated.

Table 3: Illicit trade estimate of cigarettes (in EU25)

	2009	2010	2011	2012	2013
<i>Actual consumption in million sticks</i>	734,627	705,303	665,839	635,639	596,014
<i>Illicit trade in million sticks</i>	64,397	73,664	65,612	66,883	67,780
<i>% penetration of illicit trade</i>	11.39%	13.88%	12.60%	12.79%	13.21%

Note: figures exclude Cyprus, Luxembourg and Malta

Source: Euromonitor

The existing intra EU price differences reflect, to a large degree, the differences between Member States in terms of purchasing power. Therefore, it does not seem possible, in the foreseeable future, to eliminate the economic incentives driving this form of illicit trade. In this context, it is generally agreed that a tracking and tracing system combined with a security feature becomes one of the key measures, along with the enforcement actions, to fight illicit trade.

According to the external Feasibility Study carried out at an earlier stage of this initiative (see section C for further details), the estimates (based on a lower prevalence rate of illicit trade than indicated in Table 3) show that the introduction of a tracking and tracing system combined with a security feature can reduce the number of illicit cigarettes on the EU market by approximately 368.9 million packs p.a. (i.e. 7.4 billion sticks p.a.).¹⁴

Affected stakeholders

The requirements of Article 15 of the TPD apply to all products manufactured in and/or destined for the EU market. The envisaged system covers all economic operators involved in the trading of tobacco products, from the manufacturer to the last economic operator before the first retail outlet.

The requirements of Article 16 of the TPD, i.e. to irremovably print or affix a security feature to all unit packets of tobacco products, necessarily apply to the initial stage of the production-distribution chain, i.e. to the manufacturers or the other entities responsible for placing the product on the market.

With respect to both measures, there are various groups of affected stakeholders. There is a group of stakeholders who will be affected in the deployment phase. There is also a broader group of stakeholders who will be affected once the systems for tracking and tracing and for security features are operational.

Stakeholders affected during the deployment phase:

- Manufacturers – will have to adapt the production lines in order to print or affix a unique identifier and a security feature and adapt the procedures/infrastructure to provide the information related to the unique identifier. They will also have to provide all other economic operators involved in the trade of tobacco products (before the first retail outlet) with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled.
- Importers – will have to secure that the supplies from non-EU manufacturers comply with Articles 15 and 16 of the TPD.
- Wholesalers and distributors will have to adapt their procedures in line with the tracking and tracing requirements (e.g. the entry and exit scanning of the products).
- Public authorities – will have to take the measures necessary for implementation and overview of the system deployment and to create any necessary links between the system and other parts of the control

¹³ OLAF's data, see: http://ec.europa.eu/anti_fraud/documents/eu-revenue/q_and_a_en.pdf

¹⁴ Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features (Feasibility Study), p. 273-274.
See: http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

environment.

- Suppliers of equipment and services – will be asked for the supply of equipment and services necessary in the deployment phase, including the establishment of the data storage facility(ies) for all the relevant data.
- Transport – may be, depending on the ultimate design of the system, affected in a similar way to wholesalers and distributors; however the scope of required actions may be very limited given the likely overlaps with wholesalers and distributors (e.g. the same tracking and tracing event may not need to be recorded twice).

Stakeholders affected in the operational phase:

- Manufacturers – will have to adapt to a system of printing, affixing and verifying a unique identifier and a security feature and of recording the moves of tobacco products and the related information. Their legal sales will be better protected from counterfeit and other illicit sales.
- Wholesalers and distributors – will have to record the moves of tobacco products and the related information.
- Public authorities – will have to oversee and control the operations of the system, and be able to replicate the data for systematic use in control and risk management tasks. The existence of the system is likely to create savings in terms of higher efficiency of the control measures and the cross-border compatibility of the systems. Public health will gain from the reduction of illicit trade and the consequent lower accessibility of the products not in compliance with the TPD requirements and being sold at artificially low prices. As a positive side effect, the fiscal authorities may expect an increase in the tax revenues from the legal sales.
- Retailers – will have better reassurance about the legal status of their products.
- Consumers – will have access to more controlled products.
- Suppliers of equipment and services – will service the equipment and provide other services required for the functioning of the system, including the data storage.
- Transport – may be, depending on the ultimate design of the system, affected in a similar way to wholesalers and distributors; however the scope of required actions may be very limited given the likely overlaps with wholesalers and distributors (e.g. the same tracking and tracing event may not need to be recorded twice).

Rationale for taking an action at EU level

This initiative is foreseen in EU legislation and required for the implementation of Articles 15 and 16 of the TPD. The main rationale for taking an action at EU level is explained in Recitals 29, 30 and 50 of the TPD:

"(29) Considerable volumes of illicit products, which do not fulfil the requirements laid down in Directive 2001/37/EC, are placed on the market and there are indications that these volumes might increase. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. In addition, the FCTC requires the Union to combat illicit tobacco products, including those illegally imported into the Union, as part of a comprehensive Union policy on tobacco control. Provision should, therefore, be made for unit packets of tobacco products to be marked with a unique identifier and security features and for their movements to be recorded so that such products can be tracked and traced throughout the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not tobacco products are authentic.

(30) An interoperable tracking and tracing system and security features should be developed at Union level. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow manufacturers of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and security features becoming applicable to those other products.

(50) In order to ensure uniform conditions for the implementation of this Directive implementing powers should be conferred on the Commission concerning [...] the technical standards for the establishment and operation of the tracking and tracing system, for ensuring the compatibility of the systems for the unique identifiers and for the security features, [...]"

Illicit trade has an important cross-border dimension. Tobacco products are illegally moved both within the EU and between the EU and third countries. The existence of illicit trade in tobacco products undermines the enforcement of the TPD and thus the functioning of the Internal Market, which is based on the free circulation of the compliant goods. Equally importantly the illicit trade in tobacco products undermines the health policies of Member States and reduces their tax revenues. In this context and given that Member States are also parties to the FCTC Protocol, the lack of action at EU level may lead Member States to adopt a patchwork of national

<p>solutions, which may further put at risk the smooth functioning of the Internal Market. The compatibility of the system and its cross-border functioning can be much more efficiently achieved at EU level than by means of bilateral arrangements between individual Member States. The common set of standards and rules is also likely to bolster the system's capacity to fight illicit trade, and to support effective and efficient risk-based customs supervision in the context of the <i>Common Risk Management Framework</i>¹⁵, for products coming from outside the EU.</p>
<p>Subsidiarity check</p>
<p>Legal basis</p> <p>This initiative implements Articles 15 and 16 of the TPD. The power to adopt delegated acts is conferred on the Commission by Article 27 of the TPD. Regarding the TPD, it is based on Article 114 TFEU.¹⁶ Article 114(1) TFEU empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. According to Article 114(3) TFEU, the Commission should aim at ensuring a high level of health protection in its proposal envisaged in paragraph 1 of Article 114 TFEU.</p> <p>Subsidiarity check</p> <p>A subsidiarity check was already carried out in the impact assessment of the TPD. It was noted that <i>"only a harmonised approach at EU-level can remove obstacles to cross-border trade"</i> and that <i>"only a harmonised approach would ensure that industry is not obliged to adapt at different times to [different] national regimes."</i> It was also stated that <i>"it would be very difficult for a Member State to act unilaterally due to the difficulties to enforce such an action when other Member States have different rules."</i> In this context, it was underlined that with regard to the EU system for tracking and tracing, when tobacco products regularly move across borders, <i>"a legally binding and EU wide measure [...] would [...] produce clear benefits."</i>¹⁷</p> <p>The above assessment still holds true.</p> <p>European added-value</p> <p>The EU added-value is related to providing the common set of standards and rules that will bolster the system's capacity to fight illicit trade and support effective and efficient risk-based customs supervision in the context of the <i>Common Risk Management Framework</i>, for products coming from outside the EU. The EU wide solution (whenever possible adaptable to the local requirements) is the most efficient means of assuring the compatibility of the cross-border tracking and tracing solution and the homogenous approach to a security feature required to eliminate a negative impact on the Internal Market.</p> <p>A well-functioning EU system, thanks to the critical mass of 28 Member States, will also encourage third countries to adopt compatible solutions and hence will increase the level of tobacco control both intra- and extra-EU. This would also have a positive impact on the ratification and implementation of the FCTC Protocol.</p>
<p>Main policy objectives</p>
<p>Objectives</p> <p>General objective</p> <p>To fight trade in illicit tobacco products, which undermine the free circulation of compliant products and the</p>

¹⁵ Article 46.3 of the Union Customs Code requires as follows: *"Customs controls shall be performed within a common risk management framework, based upon the exchange of risk information and risk analysis results between customs administrations and establishing common risk criteria and standards, control measures and priority control areas"* - Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code.

¹⁶ In addition to Article 95 TEC the TPD was also adopted on the basis of Article 133 TEC. Case: C-491/01 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*. [2001] ECR I-11453, the Court found, however, that Article 95 TEC was the only appropriate legal base, but that the addition of Article 133 TEC as a legal base was not a reason for declaring the Directive invalid.

¹⁷ The TPD Impact Assessment, p. 45.

protection provided for by tobacco control legislation.

To create EU systems for tracking and tracing and for security features for all tobacco products at packet level, which are being manufactured in the EU¹⁸ or imported into the EU to be placed on the EU market.

To provide for the effective implementation of Article 8 of the FCTC Protocol in the EU.

To ensure a minimum level of health protection and reducing accessibility of illegal tobacco products to young people.

Specific objectives

To develop and implement an EU tracking and tracing system of tobacco products at packet level in line with Article 15 of the TPD and as requested by the TPD.

To develop and implement a system that ensures that all unit packets of tobacco products, which are placed on the EU market, carry a tamper proof security feature composed of visible and invisible elements in line with Article 16 of the TPD and as requested by the TPD.

Link to the problem

By developing and implementing a traceability system along with security features illicit supply will be tackled by facilitating detection mechanisms and supporting European law enforcement and public health entities engaged in combatting illicit trade. It is envisaged that a comprehensive traceability solution will provide traceability and control of the distribution chain and will contribute to the functioning of the Internal Market by establishing a common control infrastructure for legitimate tobacco products.

B. Option Mapping

Baseline scenario – no EU policy change

No policy change at the EU level (conceived as a non-adoption of the implementing and delegated acts envisaged under Articles 15 and 16 of the TPD) would mean that the important measures such as product traceability and a security feature are not, or only partially, applied in the fight against illicit trade at EU level. It would undermine the TPD provisions and hence the free circulation of compliant products on the Internal Market. The EU would not also meet its obligations under the FCTC Protocol.

No EU action would likely lead Member States to adopt a patchwork of national solutions, which would put at risk the interoperability of the various solutions and thus the smooth functioning of the Internal Market.

The legally binding Agreements, including provisions on tracking and tracing, between the four biggest tobacco manufacturers and the EU and Member States ('Agreements') would continue to apply (until their expiry).

Options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation

There is no existing legislation in terms the implementing and delegated acts that would provide for the technical specifications and other key elements of the EU system of tracking and tracing and a security feature for tobacco products. Therefore, it is not possible to discuss improvements or simplification of the existing legislation.

Alternative policy approaches

The range of available solutions remains subject to the scope of the system(s) envisaged under Articles 15 and 16 of the TPD. To recall, the tracking and tracing system shall cover the supply chain from manufacturing until the last economic operator before the first retail outlet. The scope of this system includes the generating of and the marking of each tobacco packet with a unique identifier, the scanning, verifying and recording of the unique identifier (incl. possible (dis)aggregation operations), the processing, storing and deleting of data and the contracting of the data storage facility to (an) independent data storage operator(s). As to security features, they shall be tamper proof, irremovably printed or affixed on each tobacco packet, composed of visible and invisible elements.

Regarding the traceability system, given that the TPD largely fixes the scope of the present initiative, alternative policy approaches are mainly identifiable by (a) the choice of governance model, which should provide for the required level of system integrity by allocating various responsibilities and functions to individual stakeholders (in a cost-efficient manner but without undermining the objectives of the system) and (b) the selection of technical specifications that should reflect the objectives of the system with due account given to interoperability as well as to industry specific requirements.

The main choice of governance is between an industry-operated solution and a solution operated by a third

¹⁸ Products manufactured in the EU but destined for exports to third countries are excluded from the obligation to carry security features.

party. The Feasibility Study has already presented the initial set of four policy options for traceability based on either industry or third party governance.¹⁹ In addition, it is possible to propose a mixed model of governance, in which the choice of governance is separately made with respect to each distinct technological block/process (e.g. generation, printing/affixing and visual control of a unique identifier).

There are also several key choices with respect to technical specifications implying important trade-offs. The main options in this regard relate to the location of data storage, the selection of data carriers and the allowed delays in reporting tracking and tracing events (e.g. at the moment of the product's entry into a warehouse).

Regarding the security features, the Feasibility Study only proposed the options based on affixing a security feature, while other technologies integrating a security feature into the package may be also worth considering. The available alternatives for adding security features to unit packets can be broadly defined as: affixed features, non-affixed features (i.e. printed or integrated through a different method), or a combination of the first two alternatives. Regardless of which alternative is chosen, Article 16 TPD requires that a tamper proof security feature must be composed of visible and invisible elements. Regarding other technical specifications, such as a desired level of protection, they do not translate into clear-cut alternatives; they rather form a sliding scale, e.g. in terms of the level of security achieved with the selected mix of protection methods/technologies.

The above described options are summarised in Table 4 below. In addition, the table defines the basic key questions to which alternative options are designed to respond. The blocks of options A, B, C, D and S are largely independent from each other and at least at the outset, without prejudice to any further analysis required under this initiative, all their combinations are possible. Table 4 allows for coming up with multiple option sets, e.g. A2-B1-C3-D2-S1, A3-B2-C2-D1-S3, etc.

Table 4: Alternative policy options

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

Alternative policy instruments

Given the technical nature of the proposed initiative, the European standardization could be considered as alternative policy instrument. However, for the following reasons, the European standardization cannot be considered an appropriate tool in the specific context of the present initiative.

Articles 15 and 16 of the TPD give the Commission an explicit mandate to develop the "technical standards for the establishment and the operation of the tracking and tracing system" and "technical standards for the security feature". Therefore, the TPD opts for the strictly regulatory approach, as opposed to the market-driven approach on which the European standardization is based. In the absence of the implementing and delegated acts envisaged in Articles 15 and 16 of the TPD, any European standardization initiatives will be deprived of a necessary point of reference and hence of market relevance. This being said, in its work, the Commission may

¹⁹ See: http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

rely on the pre-existing standards.
Alternative/differentiated scope
<p>Articles 15 and 16 of the TPD require that the relevant measures (traceability and security features) apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to other tobacco products from 20 May 2024. The other tobacco products, e.g. cigars and pipe tobacco, are often produced or imported by smaller operators.</p> <p>As explained above, the basic scope of the initiative remains defined by the TPD and cannot be altered by means of the implementing and delegated acts.</p>
Options that take account of new technological developments
<p>Track and trace solutions and security features rely on the latest technological developments. All the proposed options require the use of the most modern technologies, including digitalisation of data, state-of-the-art developments in two-dimensional bar codes, modern printing technologies, encryption techniques and forensic technologies.</p> <p>Any solutions eventually proposed in the implementing and delegated acts will endeavour to leave sufficient flexibility to enable further improvements to the system along with the future technological developments.</p>
Preliminary proportionality check
<p>The content and form of the present initiative does not exceed what is necessary to achieve the objectives of establishing an EU system for tracking and tracing and a security feature as envisaged in Articles 15 and 16 of the TPD and in view of the international obligations of the European Union and Member States, in particular the obligations related to the implementation of Article 8 of the FCTC Protocol.</p> <p>Tracking and tracing systems are generally seen as an effective means to address the risk of diversion of genuine products into the illicit market and such systems have already been developed and used in recent years in various sectors of consumer goods. Based on information from industry an effective tracking and tracing system reduces illicit contraband by 30% in five years.²⁰ Security features are generally viewed as effective means to reduce counterfeit and the supplies of artificially cheap tobacco products, and therefore are important in terms of ensuring a high level of health protection in line with the TPD.</p>
C. Data Collection and Better Regulation Instruments
Data collection
Data requirements and collection
<p>The initiative requires an access to the specialized knowledge on tracking and tracing, and security features in the context of fighting the illicit trade of tobacco products. This type of knowledge will be acquired from (an) external contractor(s). The knowledge acquired under a contract will be completed with other important sources of information such as opinions of experts and stakeholders (see below the consultation approach) and the Commission's own research and expertise.</p> <p>The collection of the knowledge under the contract will be organised in three stages. The first stage will cover the reassessment of the Feasibility Study (see below for further details), including the options proposed therein. The second stage will cover a proposal for a concept of the optimal system for tracking and tracing, including the third party data storage. The proposed concept should define all relevant tasks/responsibilities of the various actors involved in the process along the supply chain. The third stage will concern the development of the technical standards required for the establishment and the operation of the tracking and tracing system on the basis of the proposed concept.</p> <p>At the moment of publication of the present assessment, the Commission expects to be in the first stage of the above described process.</p>
Use of available data
<p>In the context of tender n° EAHC/2013/Health/11, Eurogroup Consulting Portugal – Consultoria em gestão, LDA prepared a feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features. This Feasibility Study reaches a conclusion that full traceability of EU tobacco products is achievable. It also confirms that there are many solutions for security features that meet the TPD requirements.</p> <p>The Feasibility Study provides a large amount of information which constitutes the basis for further actions. The Feasibility Study presents four potential solutions for traceability and four for security features. Each of the proposed traceability solutions reflects the basic requirements made under the TPD, i.e. a unique identifier must be affixed to a unit packet at the manufacturing site, while information on a unique identifier along with additional</p>

²⁰ The TPD Impact Assessment, p. 108.

information required by Article 15(2), which are generated during production and distribution of tobacco products, must be saved at an independent data storage facility.

The preparatory work done for the TPD, including the related studies and impact assessment, is also a relevant source of information in the context of the present initiative.

Consultation approach

Given the technical complexity of the present initiative and in order to mitigate the associated risks, the project followed a multistage, multiparty approach to the consultations.

In the context of the Feasibility Study, the consultant identified 274 entities as potential candidates for participation in the market survey designed to obtain information directly from the track and trace and security feature industry. In total, 42 completed survey responses were received. The responses included a mix of both established and emerging organisations and technologies. The results were summarised in the Feasibility Study.

The Feasibility Study was published on 7 May 2015. On the same date, the Commission launched, on the basis of the Feasibility Study, a public consultation of the stakeholders (Targeted stakeholder consultation on the implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU)²¹. The targeted groups included manufacturers of finished tobacco products, wholesalers and distributors of finished tobacco products, providers of solutions for operating traceability and security features systems and governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade. The consultation closed on 31 July 2015.

In reply to the consultation, 109 respondents decided to submit their comments with the help of the EU survey questionnaire. The respondents represent a broad spectrum of stakeholders. The table below shows the distribution of responses according to stakeholder's self-declared main activity.

Table 5: Response rate to the targeted stakeholder consultation of the Feasibility Study

Stakeholder's main activity	Total
Manufacturer of tobacco products destined for consumers (finished tobacco products)	25
Operator involved in the supply chain of finished tobacco products (excluding retail)	19
Provider of solutions	20
Governmental organisation	12
NGO	21
Other	12
Total	109

The comments received in the course of this consultation will be an important input to the further implementation work. In particular, the comments will be taken into account in the follow-up Implementation Study.

The activities related to the Implementation Study, performed by a contractor, will include a series of consultation meetings in the form of independent expert seminars and stakeholder seminars.

Further meetings will be held with the experts designated by Member States. The Expert Group on Tobacco Policy²² set up a subgroup on traceability and security features as a forum through which Member States' experts can be consulted, in particular as regards the implementing and delegated acts under Articles 15 and 16 of the TPD.

Finally, as a part of the consultation process, an open public consultation will be also launched to receive opinions as to the key orientations for a future system.²³

Will an Implementation plan be established?

Yes No

²¹ See also: http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en.htm

²² Established by Commission Decision C(2014)3509 of 4 June 2014.

²³ Open public consultations can be found at: http://ec.europa.eu/yourvoice/consultations/index_en.htm

D. Information on the Impact Assessment Process

The Inter Service Group will be established as soon as possible and will be chaired by DG SANTE. At least, the following services of the Commission will be invited:

- Legal Service of the Commission,
- the Secretariat-General
- European Anti-Fraud Office,
- Directorate General for Taxation and Customs Union,
- Directorate General for Internal Market, Industry, Entrepreneurship and SMEs,
- Directorate General for Communication Networks, Content and Technology.

E. Preliminary Assessment of Expected Impacts

Likely economic impacts

Option Zero: no policy change

No policy change conceived as the non-implementation of Articles 15 and 16 of the TPD would undermine the TPD provisions and hence the free circulation of compliant products on the Internal Market. The EU would also not meet its obligations under the FCTC Protocol.

No EU action would likely lead Member States to adopt a patchwork of national solutions, which would put at risk the smooth functioning of the Internal Market.

The existing Agreements with the major tobacco companies do not provide for level playing field for all economic operators. Apart from the four tobacco manufactures, other manufacturers and importers do not have similar legal obligations to control the supply chain through tracking and tracing. Moreover, the scope of the tracking and tracing system adopted under the Agreements is substantially narrower in a number of important aspects, including the depth and breadth of tracking and tracing and the level of independent control.

Options for traceability and security features – general assessment

Tracking and tracing systems are generally seen as an effective means to address the risk of diversion of genuine products into the illicit market. They can also increase the security of legal supply chain from infiltrations with illicit products. Tracking and tracing systems have already been developed and used in recent years. Based on information from industry an effective tracking and tracing system can be expected to lead to a non-negligible, 30% reduction in illicit trade.²⁴ The main part of the demand, which will be diverted from the illicit segment, will go to the legal supply chain, but some smokers are also expected to reduce or stop smoking (as a result of reduced availability of illicit products), last but not least the reduced accessibility of illicit products may also reduce smoking initiation. A security feature should further reinforce the safety of legal supply chain by helping consumers and law enforcement agencies to identify illicit products.

The resulting changes in the consumption pattern bring about two immediate effects: (a) an increase in the legal sales of tobacco products along with the related increase in the amount of collected taxes, and (b) a simultaneous decrease in the overall tobacco consumption leading to the positive impact on health and important savings for the economy in terms of savings in the healthcare and improvements in the productivity (taking into account the loss of EUR 8 billion p.a. in productivity linked to smoking mentioned above).

Any proposed solution will entail the compliance and administrative costs for manufacturers, distribution chain operators and public authorities (see below for the discussion of administrative costs). The bulk of the costs will be related to the technical implementation and subsequent operations of the system. The costs for various combinations of solutions for traceability and security features assessed in the Feasibility Study were estimated to be between EUR 291 and 347 million per year (respectively 0.9-1.1 eurocent per unit marked²⁵). These costs will be further reviewed in the light of the partially critical comments received in the targeted stakeholder consultation. However, it must be stressed that any analysis of the compliance costs critically depends on the availability of such data.

²⁴ The TPD Impact Assessment, p.108.

²⁵ This compares favourably with the consumer's willingness to pay for better traceability. At least six out of ten consumers in every Member State are in favour of improving the traceability of tobacco products to reduce illicit sales, even if this makes them a few cents more expensive. See: Special Eurobarometer 429, *Attitudes of Europeans towards tobacco and electronic cigarettes*, May 2015, available at http://ec.europa.eu/public_opinion/archives/ebs/ebs_429_en.pdf

If there are any pre-existing, pre-installed technologies or technology components shown to meet the TPD requirements during the further analysis planned under this initiative, such pre-existing technologies or technology components will be duly considered provided that they meet the objectives and comply with the requirements set out in the TPD and the envisaged implementing legislation.

Individual policy options proposed in section B may differ in terms of their likely economic impacts. The below considerations are necessarily subject to further analysis:

Options A1-A2-A3 – Governance model

Option A1, in which the traceability system is largely operated by the industry, requires additional legal analysis if and how it could be made compatible with the TPD and the FCTC Protocol²⁶. As a strict minimum additional control measures by responsible authorities would be necessary which are likely to increase the cost burden on the public sector.

Option A2, in which the system is controlled by an independent third party operator, naturally diminishes a need for additional public control measures, but introduces the costs of coordination between the industry and the third party operators and potentially raises complex issues of liability.

Option A3 reflects that the costs of coordination differ depending on the nature of operations entrusted with an independent third party. The best split of responsibilities should be selected with an aim to preserve the system's full integrity (maximum impact in terms of limiting illicit products) and where possible to minimize the disruptions of the existing production and distribution schemes (minimum interference and costs).

Options B1-B2 – Data storage location

Option B1, in which the independent data storage is centralised, may, on the one hand, provide for certain economies of scale by eliminating the need for a separate central registry and for additional means to preserve cross-data-storage compatibility. The economies of scale also flow from potentially lower capital and operational costs, including less administrative overheads. On the other hand, the centralised data storage may affect access times and creates a single point of technical failure.²⁷ This option also replaces competition in the market with competition for the market, which would only take place in the beginning and possibly when a new procurement process is launched.

Option B2, in which the independent data storage is decentralised (e.g. by geography or by products), represents the reverse set of pros and cons as compared to Option B1.

Options C1-C2-C3 – Allowed data carriers

Option C1 with a single data carrier ensures, on the one hand, the highest level of compatibility, i.e. the scanners will have to be able to read only one type of data carrier. On the other hand, this solution may offer insufficient flexibility in view of different requirements of various economic operators and might reduce incentives for the development of new/innovative technologies.

Option C2 with a limited variety of data carriers should alleviate the problem of insufficient flexibility present in Option C1. It will require a pre-established list of data carriers accepted for the purpose of operating the system. Economic operators and controlling authorities will have to have scanners reading multiple types of data carriers.

Option C3, a free system allowing any existing data carrier, offers the highest flexibility in terms of applying data carriers, but also introduces a risk that certain data carriers will not be readable by all the scanners installed in the system. Its functioning would require frequent updates of the scanners, which may not be technically feasible and/or economically viable.

Options D1-D2-D3 – Allowed delays in reporting events

Option D1, which envisages real-time reporting (or limited delays), allows for very efficient tracking and tracing, which may prove to be particularly important for goods in transit, i.e. real-time reporting reduces the need for duplicating scanning operations by a dispatcher/recipient and a transport operator. It also supports effective real-time risk analysis and control decision-making, to improve the targeting of illicit trade as distinct from legitimate traffic. However, the real-time reporting requires that the scans of data carriers operate in the on-line mode and in the case of disconnecting from the system, may require additional contingency procedures. This option also means a higher frequency of data uploads that may increase the costs of operating the data storage facility(ies).

²⁶ E.g. Article 8.2 of the FCTC Protocol calls on the Parties to "establish [...] a tracking and tracing system, controlled by the Party", whilst Article 8.12 of the FCTC Protocol requires that "[o]bligations assigned to a Party shall not be performed by or delegated to the tobacco industry".

²⁷ The risks of failure may be countered with reinforced rules on contingency and back-up procedures, which naturally bring about cost considerations.

Options D2 (once a day) and D3 (once a week) require a local storage of data before a data batch is reported. Both options represent the reverse set of pros and cons as compared to Option D1 as they will likely require a bigger involvement of transport operators in the scanning operations, but will likely lower the costs related to the frequency of data uploads (Option D3 may offer higher savings in this respect). An additional complication concerning these two options relates to possible non-sequential uploads of data and risks for the system integrity.

Options S1-S2-S3 – Method of adding a security feature

Option S1, in which a security feature is affixed, was discussed in the Feasibility Study, which presented its different variants that can be used in creating an affixed security feature. The main advantage of this option is the easiness of outsourcing the manufacturing of a security feature to a third party, while subsequently the feature is affixed to the product on the manufacturing line. The main disadvantage lies in a possibility that a security feature can be removed, which may hamper the identification of genuine products.

Option S2, in which a security feature is printed or integrated with the product through a different method, allows for using a broad range of security features which are either added in a separate manufacturing process or become a part of the existing processes, e.g. special fibres are mixed with pulp to produce packet paper. The main advantage of this option is a difficulty in the subsequent separation of a security feature from the product. The main disadvantage lies in a potential need for additional controls of the processes related to security features by the authorities.

Option S3 allows for the methods proposed under Option S1 and Option S2. By broadening the range of available methods, it may be easier to obtain the necessary level of security in a cost-efficient manner. It also broadens the possibilities of rotating security features.

Likely social impacts

The TPD Impact Assessment concluded that measures in the area of “Traceability and security features” will strengthen the legal supply chain and ensure that consumers benefit from the safeguards of the TPD (such as labelling and ingredients regulation). In particular, the security feature will assist consumers in determining whether the product is authentic and hence reduce the prevalence of illicit products that do not comply with the TPD.

A reduction in the consumption of illicit products would shift in part to the legal supply chain, whereas another part is expected not to be substituted, i.e. would result in reduced overall consumption, which would in turn lead to reduced health risks and increased well-being in the long term.

It is precondition that any of the proposed solutions for both traceability and security features shall achieve the defined objectives, and to some degree reduce the number of illicit tobacco products on the EU market.

The Feasibility Study preliminary quantified the following social/health impacts associated with people quitting or reducing the tobacco consumption (assuming the 40% drop in the consumption among ex-consumers of illicit products):

- 0.6 million smokers will stop smoking;
- reduction of annual health care expenditure of EUR 134 million;
- reduction of related annual societal losses of EUR 44 million, due to:
 - reduction in smoking induced early retirements (EUR 32 million);
 - reduction in smoking-induced absenteeism (EUR 12 million).

Likely environmental impacts

No particular environmental impacts are expected.

Likely impacts on simplification and/or administrative burden

The main cost for the economic operators is related to the roll-out and subsequent operations of the system. On the basis of the feasibility study, the estimation of this cost has been provided under the likely economic impacts (see above). Given the nature of the present initiative, where the flow of information from the economic operators to the independent data storage, which is accessible to the public authorities, is at the very core of the system, it is not expected that any additional substantial reporting burdens will be necessary for the smooth functioning of the system. This analysis applies to all the alternatives except those in which the design of the system requires the authorities to introduce additional control measures to preserve the system's full integrity (see also the discussion of likely economic impacts presented above).

Likely impacts on SMEs

As explained above, the relevant measures (traceability and security features) will apply to cigarettes and roll-

your-own tobacco from 20 May 2019 and to other tobacco products from 20 May 2024. The other tobacco products, e.g. cigars and pipe tobacco, are often produced or imported by smaller operators. Therefore, many SMEs will be able to benefit from additional time and the experience gained in the first years of operating the system.

The design of the system will have to take into account the different requirements of small and big manufactures. As far as technically and operationally feasible, the proposed solutions will reflect these different requirements. Whenever possible, the system will provide for flexibility, e.g. in the choice of data carriers and the methods of incorporating data carriers/unique identifiers and security features into the products. Such flexibility should allow for minimizing the impact on SMEs.

For avoidance of doubt, the TPD introduces universal obligations and therefore, SMEs cannot be excluded from the scope of the present initiative.

Likely impacts on competitiveness and innovation

Track and trace solutions and security features 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 customized 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 certain extent taken over by non-EU countries, in particular in the context of the global implementation of the FCTC Protocol.

Likely impacts on public administrations

Governments will, independently of the chosen technical solution, benefit from the strengthened legal supply chain. A tracking and tracing system which gives the authorities access to the data storage of the independent third party, will help the authorities, to monitor systematically the movement of tobacco products at unit packet level from the place of their manufacture, through the distribution chain to the intended market of retail sale ("tracking"). The systematic real-time availability and replicability of the data can support a more effective and efficient risk-based customs supervision approach for tobacco products coming from outside the EU. It will also enable the authorities, at the time of an audit or seizure of a product, to recreate the route taken by the product from the place of its manufacturing, through the distribution chain to the point at which the product was diverted into illegal trade channels ("tracing"). Centralised storage (whether before or after replication) would help customs in both the operational and ex-post risk management and control contexts, as the ability to identify risky movements is greatly enhanced when the full supply chain history is visible, given the mobility and adaptability of the illicit tobacco trade.

As the costs of the system will be mainly borne by the economic operators, no major additional costs are envisaged for public administrations apart from necessary IT developments and a possible need to reinforce Member States' monitoring, controlling and enforcement capacities. The Feasibility Study estimated the administrative costs for Member States at the level of a single digit EUR million for operating the system. However, these costs should be considered as marginal compared to the expected benefits. It is recalled that whilst only seen as a side effect of the TPD, the measures are expected to contribute in a non-negligible way to the collection of taxes.

Likely impacts on third countries, international trade or investment

Third countries, in particular the Parties to the FCTC Protocol, will be able to adapt solutions based on the EU experience in implementing the traceability system. The EU system may create a blue print for the regional application of the traceability system.

No further impact on international trade is expected beyond the overall impact of the TPD which was notified to WHO before its adoption.