Secondary legislation under Articles 15 and 16 of Directive 2014/40/EU establishing an EU system for traceability and security features

Consultation Strategy

July 2016

1. Consultation objectives

The Commission wants to make an evidenced-based assessment of the policy options available for implementing the secondary legislation foreseen under Articles15 and 16 of Directive 2014/40EU (TPD). [1]

Articles 15 and 16 TPD establish an EU-wide tracking and tracing and security feature system for all unit packets of tobacco products manufactured in or imported into the Union. The aim of this system is to fight illicit trade in tobacco products, which undermines the free circulation of compliant products and the overall protection provided by tobacco control legislation.

According to Article 15 TPD, all unit packets of tobacco products manufactured in or imported into the Union must be marked with a unique identifier (containing defined data elements) and their movements must be recorded throughout the supply chain (up to the last level before retail). 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.

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.

Although the central requirements have been laid down in the TPD, Articles 15(11), 15(12) and 16(2) require the Commission to adopt secondary legislation to determine the technical details and key elements of the system, as well as to ensure aspects such as the system's interoperability.

In order to ensure that the preparation of the above-mentioned secondary legislation is evidenced-based, that the Commission's information needs are covered and that the views of relevant stakeholders are taken into account, the Commission has foreseen various consultation methods and tools. The main objective of these consultations is to gain key feedback on the various policy options under consideration, and in particular to gain insight into which policy option(s) is/are most likely to achieve the objectives set out in the TPD in a manner that is cost-efficient and that imposes least burden on stakeholders concerned.

The feedback gathered throughout the consultation exercises foreseen will feed into the impact assessment process and the preparation of the secondary legislation, and provide important orientation for the measures to be adopted.

2. Stakeholder mapping

There are various stakeholder groups who will be affected by the measures foreseen. These should be taken into account in order to define the appropriate consultation strategy.

Some of these stakeholders will be affected in deployment phase, whilst others will be affected once the systems for tracking and tracing and for security features become operational. The below list maps the principle stakeholders concerned and identifies the key points at which they are likely to be impacted:

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

[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.

equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled.

- **Importers** – will have to ensure 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 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).

3. Consultation methods and tools

The following methods and tools of gathering information and opinions will be applied in the context of the present initiative:

- **Feasibility and Implementation Studies**: an important contribution to the preparatory work will come from the Feasibility[2] and Implementation Studies, for which high level external consultants have been engaged by the Commission. These analyse respectively the feasibility of the system established under the TPD and how it might concretely be implemented. Consultations of key stakeholders will give important input in the context of both of these studies, by providing expert opinion, data and feedback.

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[2] http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

As part of the Implementation Study, the consultant will further analyse the feedback received from key stakeholders to date, including during the market survey carried out in the course of the Feasibility Study and during the targeted stakeholder consultation carried out by the Commission (see below). In addition, stakeholders will be consulted via targeted stakeholder workshops (see below) and individual contact will be taken where necessary.

- **Market survey**: The objective of the survey was to gather opinions, data and feedback directly from the track and trace and security feature industry. The consultant conducting the Feasibility Study identified 274 entities as potential candidates for participation. 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 and showed that the EU system for tobacco traceability and security features is technically feasible.

- **Stakeholder consultation**: a targeted stakeholder consultation was carried out in 2015 by the Commission. This was aimed at stakeholders with key technical experience in the field including manufacturers, wholesalers and distributors of finished tobacco products, solution providers of traceability and security features systems and governmental and non-governmental organisations active in the area of tobacco control and illicit trade. The consultation was based on the findings of the Feasibility Study and the aim was to provide key opinions, data and feedback from a broad range of stakeholders. Over 100 responses were received from a broad spectrum of stakeholders. These responses were individually reviewed and, where possible, published.[3] The feedback from the stakeholder consultation will continue to be taken into account over the course of the preparatory work (including further in-depth analysis during the Implementation Study).

- **Open online public consultation**: A 12-week open online public consultation will be carried out and hosted on the Europa website *Your Voice in Europe*. The public consultation will be open to all interested parties. The answers will feed into the impact assessment process and the preparation of the secondary legislation. E-mails will be sent to relevant stakeholders to raise awareness about the consultation. The consultation is currently planned to run **from July to October**.[4] The findings from the consultation will be summarized in a synopsis report and published on the consultation website.

  The main aim of this public consultation is to seek input on the various policy options currently envisaged for implementing the measures foreseen under Articles 15 and 16. These have recently been further developed in the **Inception Impact Assessment**[5]. This document will form the basis for the questions to be posed and those participating in the public consultation will be advised to review it before responding.

  Through this consultation, the Commission hopes to gain feedback regarding the relevance and impact that the various policy options outlined in the Inception Impact Assessment would have. In particular it will aim to:

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

- **Workshops with independent experts**: These are foreseen at various intervals throughout

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

[4] Interested stakeholders and citizens are advised to check the website of *Your Voice in Europe* on a regular basis for the launch of the public consultation, see: http://ec.europa.eu/yourvoice/consultations/index_en.htm

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

the development of the Implementation Study and are designed to provide expert independent analysis and perspective to orient the work being carried out by the consultant. The independent experts will be selected and recruited by the Commission based on their key technical (or other) experience in fields related to the development and implementation of traceability and security features. In order to provide maximum added value, these have been scheduled for strategic junctures in the course of the study.

- **Workshops with stakeholders**: In a similar manner, workshops with stakeholders – including manufacturers of tobacco products, solution providers and NGOs active in the field – have been foreseen and will take place at key points throughout the Implementation Study. The aim of these workshops is to present key aspects of the study's work to stakeholders, so as to gain key technical perspective and input. Two workshops with stakeholders have been planned. Provisional dates are 12/12/2016 and 15/05/2017. Although capacity will be limited the Commission will endeavour to accommodate as many participants as possible and all interested parties are invited to signal their interest.[6]

- **Expert Subgroup**: Member State authorities will be regularly consulted via the Expert Subgroup on Traceability and Security Features (established by the Expert Group on Tobacco Policy[7]). The most recent meeting of the Subgroup took place on 22 June 2016 and further meetings have been scheduled for all key points in the process. At these meetings, Member State authorities will be given the opportunity to provide key regulatory perspective and input in the shaping of the secondary legislation.[8]

6 Stakeholders who did not participate in the stakeholder consultation carried out in 2015 and are interested in attending the workshops are asked to contact: SANTE-B2-TOBACCO-CONTROL@ec.europa.eu

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

8 Minutes of the meetings of the Expert Group are published at: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor2