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EXECUTIVE SUMMARY OF THE 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) 455 final} -
{SEC(2017) 531 final}

Executive Summary Sheet

Impact assessment on the Implementing acts under Articles 15(11) and 16(2) of the Tobacco Products Directive (TPD) 2014/40/EU

A. Need for action

What is the problem and why is it a problem at EU level?

The problem is illicit trade in tobacco products, the level of which remains high in the EU. Illicit tobacco products are not compliant with tobacco control legislation and provide artificially cheap supplies of tobacco that affect the uptake and prevalence of smoking. Articles 15 and 16 of Directive 2014/40/EU (TPD) aim to address this by providing for systems of traceability and of security features for tobacco products in the EU to secure the supply chain and facilitate product authentication. The provisions on traceability (Article 15) require all unit packets of tobacco products produced in, destined for or placed on the EU market to be marked with a unique identifier and their movements recorded throughout the supply chain (from the manufacturer to the last level before the retail outlet). The provisions relating to security features (Article 16) require all unit packets of tobacco products placed on the EU market to carry a security feature to facilitate their authentication. The Commission is required, via implementing acts, to lay down technical specifications for the establishment and operation of these systems.

These acts should address the following issues:

1) marking of packages with a unique identifier;

2) recording and transmission of data to a data storage facility;

3) processing, storing and accessing data;

4) compatibility of components of the traceability system; and

5) technical specifications for security features.

What should be achieved?

The measures are expected to enable the smooth functioning of the single market while ensuring a high level of health protection. They will also enable the EU to meet its international obligations under Article 8 of the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.[1]

What is the value added of action at the EU level?

Harmonised implementation of the systems of traceability and of security features across the EU will be ensured, enabling Member States to meet their obligations under the TPD and the FCTC Protocol. Member States will be able to ensure the systems function in a workable and interoperable manner, coherent with the smooth functioning of the single market.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

The TPD requires the Commission to adopt implementing acts to address the main outstanding issues related to the systems to be established. These and the various policy options to address them are set out below.

1a. Marking packages with a unique identifier: This issue is at the core of the traceability system. A proper assignment of responsibility related to the marking of packages is central, for meeting the requirement for authorities to control the system (FCTC Protocol).

Policy options assessed:
1a/1: Industry operated model;
1a/2: third party operated model;
***1a/3*: mixed solution model**.

[1] See: http://apps.who.int/iris/bitstream/10665/80873/1/9789241505246_eng.pdf?ua=1&ua=1The Illicit Trade Protocol was adopted by the Conference of the Parties to the FCTC in November 2012. In addition to the EU, at the time of drafting, six EU Member States have ratified the Protocol: Austria, France, Latvia, Lithuania, Portugal and Spain.

1b. Recording and transmitting data: a key consideration is the time that elapses between an event and its transmission to the data storage system(s). TPD does not define rules on this.

Policy options assessed:
***1b/1*: near real-time time lag**;
1b/2: one day time lag;
1b/3: one week time lag.

1c. Processing, storing and accessing data: secure data storage that offers full accessibility to competent authorities is essential.

Policy options assessed:
1c/1: decentralised storage per manufacturer/importer;
1c/2: decentralised storage per Member State;
***1c/3:* combined model**.

2. Compatibility of components of the traceability system: to facilitate the scanning process for economic operators, information should be encoded on tobacco packages in a pre-defined way. The authorised variety of data carriers should be defined.

Policy options assessed:
2/1: single data carrier per packaging level;
***2/2:* limited variety of data carriers per level**;
2/3: a free system.

3. Security features: the method of applying security features is important for ensuring that they are able to fulfil their function, meet TPD requirements and allow for innovation.

Policy options assessed:

3/1: printing or affixing;
***3/2*: printing or affixing or a combination of printing and affixing**.

(*Preferred options are marked in bold*)

What are different stakeholders' views? Who supports which option?

For issue **1a)** most economic operators favoured option 1a/1. Public health organisations and many solution providers favoured option 1a/2. Member States generally favoured option 1a/3.

For issue **1b)** most economic operators favoured option 1b/2. Public health organisations and many Member States favoured option 1b/1. Option 1b/3 was generally considered less effective.

For **1c)** economic operators generally supported option 1c/1. Many Member States and public health organisations stressed importance of a centralised overview of data (as per option 1c/3).

For **2)** and **3)** stakeholders generally agreed that the most suitable options were 2/2 and 3/2, respectively.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

They are expected to deliver considerable social and economic benefits estimated at EUR 3.8 billion per year. This will happen through a reduction in illicit tobacco products in circulation in the EU. While part of this will be substituted by increased legal sales, it will also lead to a decrease in total tobacco consumption (by 0.6 %), thereby contributing to protecting public health. Increased legal sales will increase tax revenues and profits for economic operators.

What are the costs of the preferred option (if any, otherwise main ones)?

The annualised costs are estimated at EUR 159 million, including EUR 138 million for the traceability system. This includes the establishment and operation costs. It is assumed that economic operators will incur the bulk of the costs, which are estimated at EUR 155 million. The unit cost of the traceability system is estimated at below half a eurocent. This is unlikely to translate into meaningful increases in the price of tobacco products

manufactured in the EU.

What are the impacts on SMEs and competitiveness?

SMEs may be more affected by the costs of implementing the systems than larger companies. Acknowledging this, the TPD provides for a longer transitional period for tobacco products *other than* cigarettes and roll-your-own tobacco, whose manufacturers are often SMEs[2], meaning they have longer to adapt. An additional transitional period for SMEs is likely to be envisaged, e.g. in relation to the time lags for recording and transmitting data. Positive unintended consequences in competitiveness and innovation in the sector providing traceability and security feature technologies are expected.

Will there be significant impacts on national budgets and administrations?

The measures are expected to result in an additional EUR 2 billion per year in collected taxes (i.e. VAT and excise duties). As to costs, the competent authorities are expected to incur around EUR 4 million per year.

Will there be other significant impacts?

The unit cost of the traceability system is estimated at below 0.5 cents. This is unlikely to mean meaningful increases to prices of tobacco products manufactured in the EU. Therefore, the measures are not expected to have negative impact on international trade or the competitiveness of the EU tobacco industry.

Proportionality

The proportionality of all the options was evaluated by assessing the extent to which they:

1) are suitable to achieve the operational objectives identified;
2) are necessary to achieve these objectives; and
3) allow these objectives to be achieved at maximum benefit and minimum costs.

The options best meeting the above criteria were identified as preferred. In assessing the preferred options, estimated benefits versus estimated costs were taken into account.

D. Follow up

When will the policy be reviewed?

Article 28 of the TPD requires the Commission to submit a report to the European Parliament and to the Council no later than five years from 20 May 2016.

[2] Article 15(13) of Directive 2014/40/EU sets out that the systems for traceability and security features should 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.