

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

Fields marked with * are mandatory.

This is a targeted stakeholder consultation. The purpose of this consultation is to seek comments from stakeholders:

- directly affected by the upcoming implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the new Tobacco Products Directive (Directive 2014/40/EU), or
- considering to have special expertise in the relevant areas.

In the Commission's assessment, the following stakeholders, including their respective associations, are expected to be directly affected:

1. manufacturers of finished tobacco products,
2. wholesalers and distributors of finished tobacco products,
3. providers of solutions for operating traceability and security features systems,
4. governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade.

Not directly affected are retailers and upstream suppliers of tobacco manufacturers (except the solution providers mentioned in point 3 above).

The basis for the consultation is the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFFEA) in response to tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter the Feasibility Study). The Feasibility Study was published on 7 May 2015 and is available at http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf. The interested stakeholders are advised to review the Feasibility Study before responding to this consultation.

The comments received in the course of this consultation will be an input to the further implementation work on a future EU system for traceability and security features. In particular, the comments will be taken into account in a follow-up study.

Stakeholders are invited to submit their comments on this consultation at the following web-address <https://ec.europa.eu/eusurvey/runner/trace> until 31 July 2015. The web-based survey consists of closed and open questions. For open questions stakeholders will be asked to provide comments up to the limit of characters indicated in the question or to upload (a) separate document(s) in PDF format up to the limit of total number of standard A4 pages (an average of 400 words per page) indicated in the question. Submissions should be - where possible - in English. For a corporate group one single reply should be prepared. For responses from governmental organisations, which are not representing a national position, it should be explained why the responding body is directly affected by the envisaged measures.

The information received will be treated in accordance with Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Community (please consult the [privacy statement](#)). Participants in the consultation are asked not to upload personal data of individuals.

The replies to the consultation will be published on the Commission's website. In this light no confidential information should be provided. If there is a need to provide certain information on a confidential basis, contact should be made with the Commission at the following email address: SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu with a reference in the email title: "Confidential information concerning targeted stakeholder consultation on the implementation of an EU system for traceability and security features". A meaningful non-confidential version of the confidential information should be submitted at the web-address.

Answers that do not comply with the specifications cannot be considered.

A. Respondent details

*A.1. Stakeholder's main activity:

- a) Manufacturer of tobacco products destined for consumers (finished tobacco products)
- b) Operator involved in the supply chain of finished tobacco products (excluding retail)
- c) Provider of solutions
- d) Governmental organisation
- e) NGO
- f) Other

*A.1.b. Please specify:

- i) Importer
- ii) Distributor
- iii) Wholesaler
- iv) Warehouse operator (unless part of 1a of 1bi, ii or iii)
- v) Other

- *A.2. Contact details (organisation's name, address, email, telephone number, if applicable name of the ultimate parent company or organisation) - if possible, please do not include personal data

Text of 1 to 800 characters will be accepted

Lyfra nv
Kapelstraat 100
2160 Wommelgem
Belgium
+32 3 3553110
info@lyfra.be

- *A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):

Yes No

- *A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.

• [9e6db90d-22a6-4e68-b876-cf8b25ae0b89/SWOM-MFP-SA15073114350.pdf](#)

B. Options proposed in the Feasibility Study

B.1. Please rate the appropriateness of each option for tracking and tracing system set out in the Feasibility Study in terms of the criteria listed in the tables below

B.1.1. Option 1: an industry-operated solution, with direct marking on the production lines carried out by tobacco manufacturers (for further details on this option, please consult section 8.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B.1.2. Option 2: a third party operated solution, with direct marking on the production lines carried out by a solution or service provider (for further details on this option, please consult section 8.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.3. Option 3: each Member State decides between Option 1 and 2 as to an entity responsible for direct marking (manufacture or third party) (for further details on this option, please consult section 8.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.4. Option 4: a unique identifier is integrated into the security feature and affixed in the same production process (for further details on this option, please consult section 8.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)

- **96cd52be-0241-4ecf-9b72-864dee5ba418/Introductory remarks options.docx**

B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below

B.2.1. Option 1: a security feature using authentication technologies similar to a modern tax stamp
 (for further details on this option, please consult section 9.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.2. Option 2: reduced semi-covert elements as compared to Option 1 (for further details on this option, please consult section 9.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.3. Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection (for further details on this option, please consult section 9.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.4. Option 4: security feature is integrated with unique identifier (see Option 4 for traceability)
 (for further details on this option, please consult section 9.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

C. Cost-benefit analysis

C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*The cost analysis presented in section 11.3.2 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

*C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please upload your main reasons for disagreement (max. 5 pages)

- 1b74f1f6-0e7f-46a2-b5a4-579ff4bc1dc7/Costs to economic operators.docx

D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16). When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.

*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single standard provided by a relevant standardization body
- b) A public accreditation or similar system based on the minimum technical and interoperability requirements that allow for the parallel use of several standards;
- c) Another solution
- d) No opinion

*D.1.a. Please indicate your preferred standardization body

Text of 1 to 400 characters will be accepted

```
GS1 standardization body for using IDs and data carriers:  
pack: sGTIN ( GTIN+serial number)  
carton/bundle: sGTIN-DataMatrix  
master case/pallet: sGTIN- GS1-128
```

*D.1.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

```
Codentify is an operational solution for combatting illicit trade,  
combining Product Authentication and Track&Trace technologies, by  
generating a unique number to serialise the consumer unit. It is based  
on advanced, highly secure digital coding technology and offers  
visibility and control over global supply chains. The information that is  
embedded in the code can be retrieved from the system and includes a  
variety of information. A machine-readable version of the code, that  
contains the same information, is also printed on the pack for scanning:  
called the DOT Code.
```

D.2. Please upload any additional comments relating to the rules for generation of a serialized unique identifier referred to in question D.1. above (max. 2 pages)

• **e101e829-5a6f-44ae-b4bc-ecb96894af3d/Speculations regarding unique identifiers generated by the manufacturers.docx**

*D.3. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) Solution based on a single data carrier (e.g. 1D or 2D data carriers)
- b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers;
- c) Another solution;
- d) No opinion

*D.3.a. Please indicate your preferred data carrier and explain why

Text of 1 to 400 characters will be accepted

..

*D.3.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

There is not only one data carrier that may cover different packaging hierarchies and be compliant with EUTPD.
For the lowest packaging unit (e.g. pack of cigarettes, pouch, tin) the ISS DotCode is the only available symbology that allows to apply human and machine-readable codes during high-speed production. At the next level (outers/cartons) the GS1 DataMatrix is printed.
Both on Master Cases and Pallets the GS1-128 barcode is applied.
According to the 'Analysis and Feasibility Assessment, GS2 data carriers are the most widely used ones in the supply chain.

*D.4. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) System only operating with machine readable codes;
- b) System operating both with machine and human readable codes;
- c) No opinion

D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)











*D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?

- a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
- b) After a pack/tin/pouch/item is folded/assembled and filled with products;
- c) No opinion

D.7. Please upload any additional comments relating to the placement of a serialized unique identifier referred to in question D.6. above (max. 2 pages)

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Verifying if products are properly marked on the production line	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon dispatch from manufacturer's/importer's warehouse	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon receipt at distributor's/wholesaler's premises	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*Scanning products upon dispatch from distributor's/wholesaler's premises					
*Aggregation of products					

D.9. In relation to question D.8. above, please specify any other measures that your organisation considers relevant

Text of 1 to 1200 characters will be accepted

*D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A security feature is affixed;
- b) A security feature is affixed and integrated with the tax stamps or national identification marks;
- c) A security feature is printed;
- d) A security feature is put on the pack/tin/pouch/item through a different method;
- e) No opinion

*D.10.d. Please explain your other method

Text of 1 to 800 characters will be accepted

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D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)

• **5e040485-f296-40f5-aac1-2e15d111019f/Security features.docx**

*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single centralised storage for all operators;
- b) An accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory);
- c) Another solution
- d) No opinion

D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)

*D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)?

- a) Provider of solutions to collect the data from the manufacturing and distribution chain;
- b) Provider of data storage services;
- c) Another entity
- d) No opinion

*D.14.c. Please explain

Text of 1 to 800 characters will be accepted

D.15. Please upload any additional comments relating to the development of reporting and query tools referred to in question D.14. above (max. 2 pages)

*D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)?

- a) Yes
- b) No
- c) No opinion

D.16.b. If no, please explain your considerations

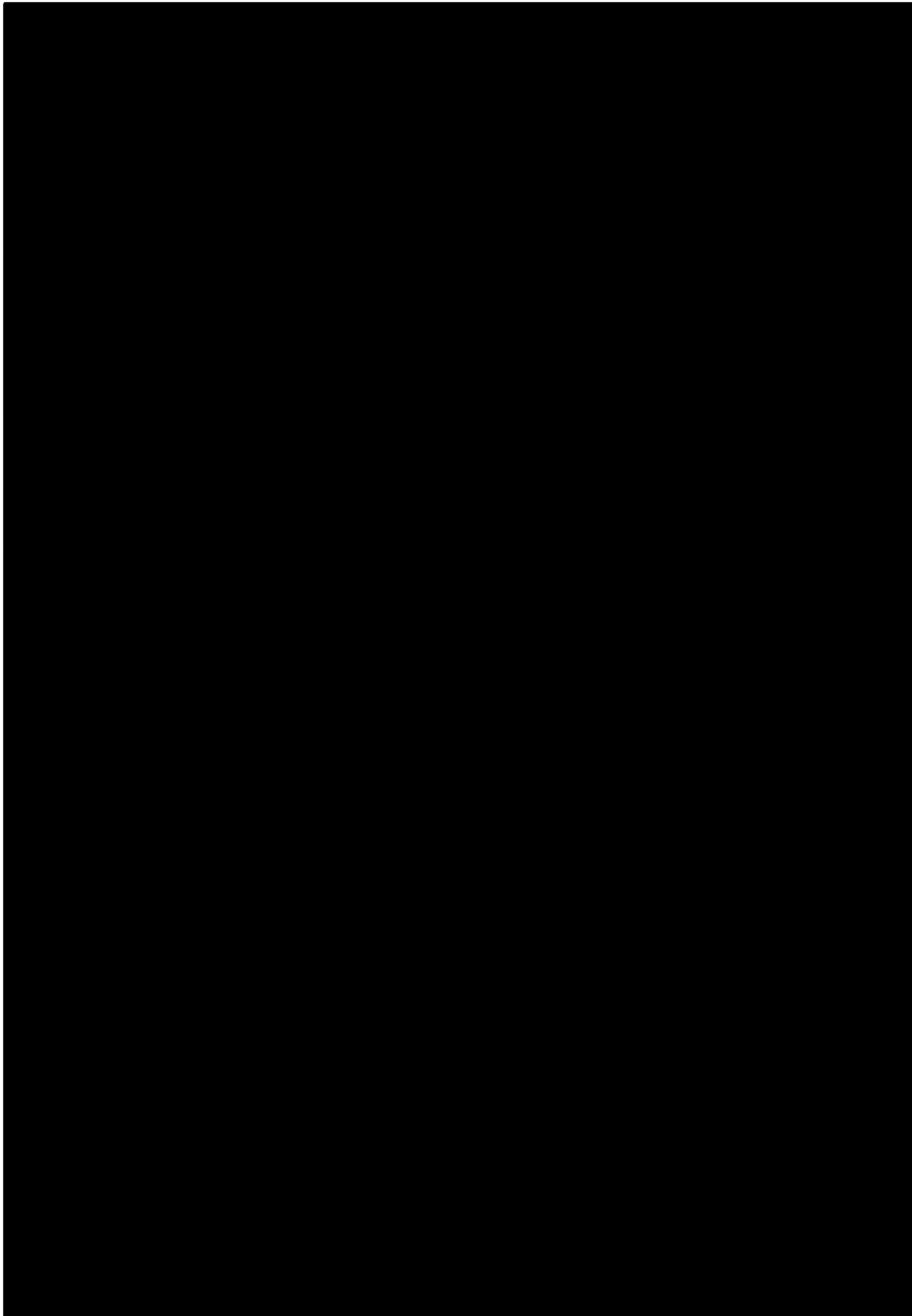
Text of 1 to 800 characters will be accepted

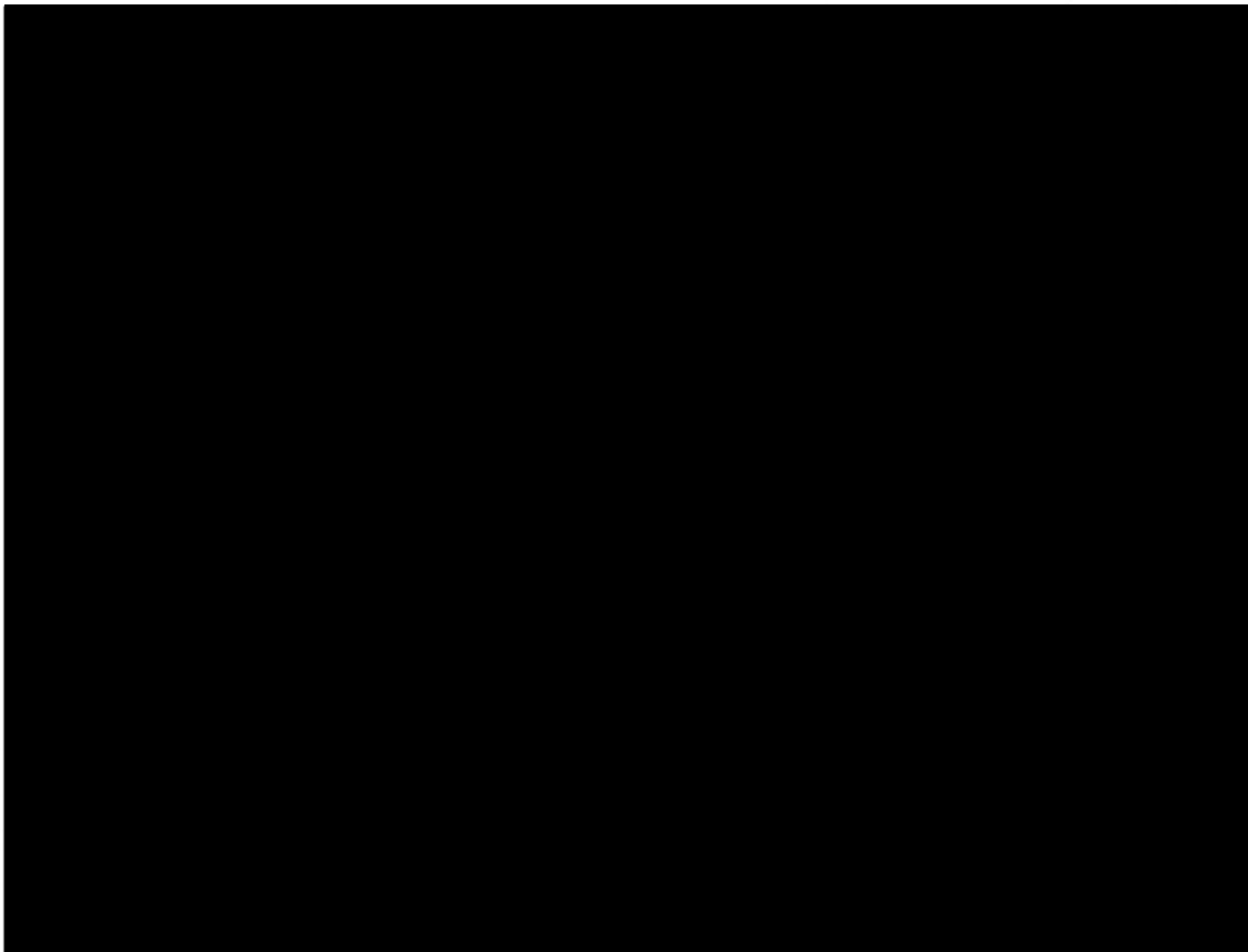
for authentication purposes
consumer

D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)

Contact

✉ SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu





Introductory remarks

The requirement of an EU tracking and tracing system and security feature for tobacco products represents a multibillion euro industry. Therefore careful measures have to be put in place to ensure an objective assessment of facts to protect the process from the vested interests of any industry or individual company.

The feasibility study (hereafter “the study”) significantly underestimates the complexity and cost of implementation for manufacturers, traders and logistic providers of these proposed solutions. It includes flawed methodologies and conclusions, and provides an unbalanced evaluation favouring monopolistic solutions.

First and foremost, we consider the lack of any overall concept as the most obvious shortcoming of the study. Important questions are not addressed, such as the obligations of warehousing and transporting companies, retail organisations, EU exporters and non-EU economic operators for imports and exports. Furthermore, the responsibility and technical feasibility of shipment route reporting is also unclear. Previous relative clarity on reporting of customer identification, order and invoice number and payments has been replaced with naïve and non-compliant suggestions.

In summary, instead of focusing on the feasibility of implementing the adopted legislation, the study undermines it: promoting unrealistic solutions which do not meet the regulatory requirements, and calling for several additional feasibility studies and increasing the level of uncertainty for all stakeholders.

Options 2, 3 and 4 for Tracking and Tracing (T&T)

Option 2 is a proposal for a monopolistic (or oligopolistic) EU-wide solution, under which one or more “independent” solution providers (SP) develop the EU T&T solution and manage the data collection at manufacturer premises (including non-EU locations manufacturing for imports into the EU).

The description alternatively refers on pages 160, 161, 173 and 174 to one or more solution providers and to one or more Data Management Providers (DMP), leaving open what the concept of several SPs and DMPs really is and how it could work.

Under option 3, Member States would appoint a monopolistic national DMP. Under sub-option 3a, manufacturers would collect and transfer data to a national database. Under sub-option 3b, an appointed national “independent” SP would supply and operate the technology and a national DMP the data storage.

Under option 4, to achieve “Further synergies and cost savings”, each MS would appoint a provider of security features which also include pre-printed unique identifiers. An appointed national SP would supervise the application of security features on packs and transmit data to a national database operated by appointed DMP. On the other hand, manufacturers would be responsible for unique identifiers on the higher packaging levels (cartons/mastercase), for aggregation data and reporting of events (movements/sales).

Shortcomings of options 2, 3 and 4

Legal aspects

In our view, there are at least 10 legal aspects to be considered.

As Directive 2014/40/EU (EUTPD) only authorises the Commission to determine 'technical standards' and 'key elements of data storage contracts', it does not include any authorisation of the Commission or the Member States to appoint:

- any specific technology or solution provider (SP)
- any solution operator
- any data management provider (DMP)

Further, the automatic exclusion in options 2, 3 and 4 of developed and implemented T&T systems, which are based on legally binding agreements between the four largest manufacturers and the EU, may give rise to legal issues.

In our view, Art. 15 of the EUTPD clearly refers to one database per manufacturer, hosted by an independent third party and monitored by an independent auditor (selected by the manufacturer and approved by the Commission).

There is no obvious definition of 'independent' provider or operator. All relevant companies in this field have been suppliers of tobacco manufacturers.

The specification of a certain supplier of the T&T solution constitutes a Technical Barrier to Trade (TBT) under the WTO agreements, as it excludes non-EU manufacturers from accessing the EU market unless they use EU appointed suppliers, which is a discriminatory practice providing a competitive advantage to EU manufacturers. For the implementation and operation, we would expect complex liability issues if the solutions are not implemented on time or do not work properly.

All these options would also require excessive legislation for:

- Rights and obligations of all stakeholders, for initial and operational payments regarding the mandatory use of products/services of all different providers including specific issues such as imports, exports, warehousing and transport of tobacco products.
- Specification of functionality of the system(s) and offer of equipment choices
- Accountability for incomplete and inaccurate data (data integrity) including all specific issues such as different regimes for economic operators (mandatory use of appointed technology providers and operators for manufacturers, voluntary use for the trade) and non-EU located economic operators.
- Legal issues regarding mandatory supply (and potential leak) of highly sensitive commercial information to commercial "independent" third parties (data security).
- Issues around the mandatory presence of commercial "independent" third parties in manufacturing premises that are, in addition, tax warehouses.
- Legal aspects of FCTC Protocol provisions which require systems "controlled by the Parties" instead of "independent" third parties.

Option 4 (pre-printed identifier on security features) is non-compliant with Art 15(3) and the FCTC Protocol.

A mandatory monopolistic EU solution would lead to the non-compliance of EU exports with the legislation (markings, technology, unique identifiers) of the destination market unless two technologies are used at the same time. Under option 4, two stamps could even be necessary.

Organisational aspects

All options requiring the appointment of a solution/data management provider or operator would require public tenders that could not start before the adoption of implementing acts (optimistic date: Q2 2017). The preparation of detailed tender(s) would take years if it were to ensure that the solution covers all EU requirements and that national solutions are based on the same structures of unique identifiers, data collections, databases, transfers and reports.

The study confirms that there is no existing 'independent' system in operation (only the systems of tobacco manufacturers). SCORPIOS, developed by the Swiss security provider SICPA and operated in Brazil, is a system which manages the distribution of tax stamps, not products. The study also admits "some concerns related to the fit of the solution in the TPD context: The current implementation in Brazil does not track tobacco products beyond point of tax payment, which is the manufacturer. Tracking beyond this point would require additional development". To that extent, the tender(s) would have to select a winner based on an unapproved capability to develop a potential solution within assumed time and costs.

Some further concerns regarding transparency and business practises surrounding the selection of this monopolistic solution have also been expressed by investigators and prosecutors in Brazil.

If developed and proved to be workable, the solution would have to be implemented by the solution provider(s) in at least 230 EU manufacturing companies on 745 EU cigarette manufacturing lines. All of these companies would have to integrate the future solution(s) with their existing Enterprise Resource Planning (ERP) software to provide manufacturing order information, with administration systems for invoicing information and accounting systems for payment information. once companies producing other tobacco products and companies with manufacturing lines outside of the EU are taken into account, this situation becomes even more complex.

There are also at least 2,450 wholesale companies operating 7,690 warehouses, 1,944 vans for vending machines and 3,699 sales vans using mobile IT solutions which would also require integration. There are probably many more parties affected, as the study excluded all retailers with T&T obligations, such as retail chains. It is extremely unlikely that such work could be realised within the next couple of decades.

Solutions 2, 3b and 4 require the permanent (supervised) presence of "independent" solution providers or operators at manufacturing premises (which would extend around the globe should they manufacture for the EU market).

Technology aspects

Certain statements demonstrate that the study are not grounded in reality and that the authors have no expertise in basic administrative procedures. For example, to provide “indications that the volume of tobacco products at a particular location exceed the capacity of the facility” would require stock accounting and information on maximum capacity for all possible combinations of different product categories for any single warehouse.

Similarly, “automated checking of value of goods vs. adequate bond” would require the information on excise applicable for each pack, as well as the inclusion of all excise payments, as the outstanding excise is the balance between excise obligations and payments. The proposals under 8.6.8 (linkage to EU Customs and Excise systems) are similarly unrealistic.

To avoid up to 28 technologies (one per EU market) being applied on the same manufacturing line, the study suggests in 8.6.4 (p. 217) that the system selected by the manufacturing country (options 3b and 4) would apply for all products including those sold in other EU markets. This may solve the issue in the factory, but as a consequence (a consequence that the study does not address), products sold in a given MS would be tracked and traced by up to 28 different technologies.

The study does not clarify which data storage would apply (manufacturing/destinationmarket) but all possible solutions would lead to even more chaos. Also, a manufacturer with factories in different MS would have to deal with individual national technologies, providers and operators. It is also unclear which technology and national database would apply for non-EU manufacturers. The most bizarre consequence would be that up to 28 different security features could be present on the market of a given MS, as option 4 is a combination of security features and unique identifiers. It is very likely that the expert project team overlooked this complexity, as this was accompanied with the suggestion that national tax stamps would also apply. The study significantly underestimates the data size for 30bn unique identifiers, aggregation, disaggregation and events (movements and sales). The study admits that only two years of data would be accessible online, whereas the FCTC Protocol requires four years, and the study itself even cites seven years as being necessary. Therefore, we consider the single EU data storage option to be unrealistic.

We also consider the national databases as unrealistic, as there is no practicable way to implement 28 identical structures (and concepts to store the data) and to develop software to recreate the cross-border products events (i.e. movements and sales) from these 28 databases. Using ill-designed methodology, the study calculates that around 5% of EU products are manufactured and sold in different MS. In fact, the real share is at least 10 times higher, making it necessary to recreate the journey of the majority of products from different databases. Unfortunately, the study does not make any further feasibility analysis beyond the humble statement: “[the] EU operates a query messaging service for the routing of tracing queries that span multiple Member State data repositories”.

Realising the limits of option 4 for export products, the study suggests that special methods be used to generate printed identifiers for exports or, preferably, the use of export stamps. The study has clearly failed to recognise that this would lead to two stamps, two technologies and two identifiers for exports markets that apply national stamps and rules for T&T. With space on packs being very limited, the two stamps would most likely have to be in the same location as well.

The study regularly ignores adopted legislation. In the case of customer identification, customer order, invoice number and payments the proposals are not compliant with Art 15(2) and the FCTC Protocol. The requirement of the legislation is clear and simple: each identifier has to be linked to these four data elements and transferred to the databases. The solution suggested by the study, to have this information stored by the economic operator and to utilise the unique identifier as a key for the records, would put the entire EU T&T system into question. If customer identification is to be provided under this suggestion, so could the order and invoice number. If the customer information was not provided, the entire T&T system would be useless. Even more remarkably, the access of manufacturers to the unique identifiers is considered by other parts of the study as being key in ensuring the integrity of the T&T system is not compromised, [thus contradicting EUTPD art. 15.8, para 3]. The other alternative, which suggests a pdf copy of an invoice and payment, supports the conclusion that this study is full of contradictions and is at best naive.

Lastly, the study does not make any suggestions as to the feasibility of intended and actual shipment routes and the responsibility to report on these.

Option 1

Advantages of option 1

We consider option 1 as being the only option which is compliant with existing legislation, capable of being implemented on time and is technically feasible. Under this option, all manufacturers can design a system based on their manufacturing equipment, product category, speed of lines, company size, degree of automation and IT infrastructure, using local suppliers, local languages and providing local service. This solution is also best placed to accommodate requirements of export markets (in the worst case using separate lines and equipment).

These systems are in operation in 160+ countries (at least at carton and master case level, and partly already at pack level) and some software components are even available for free (e.g. Codentify software to generate and store the identifiers). Over the last 10 years, several independent suppliers and consultant companies have collected a significant amount of expertise to support the remaining manufacturers in implementing a tailored solution.

Under this option, all data concerning a product are in the same database (manufacturing, aggregation, events) and the manufacturer has to ensure that reporting tools are in place. To ensure interoperability, the Commission simply has to adopt minimum technical standards, as there is no need for full alignment of structures and concepts. Only identifiers, data transfer and reports have to be standardised. For coding of identifiers on cigarette packs, the ISS Dotcode for high-speed packaging lines. For all other products and packaging, the GS1 standard data carriers are the most suitable solution. For the data transfer between the trade and data storage, the GS1 EPCIS data transmission standard is the best and most suitable solution.

Finally, there is no need for any stock-keeping unit (SKU) reporting (p.141) as individual manufacturers can maintain their own master data (for products and customers).

Costs to other economic operators

The underestimation of investments by other economic operators is even more significant. The assumption that in fully automated high speed warehouses three individuals with hand-held scanners could cover all T&T requirements is at best naïve. The integration of T&T systems with other IT systems to provide all required data has also been ignored. Based on a pilot with a (medium-sized?) wholesaler in Germany, around €250,000 of investments would be required to implement the T&T system and incorporate it into the IT infrastructure. The time it takes to distribute a customer order also increased by 60%.

The investments for smaller distributors will be lower, but nevertheless still significantly above the investments assumed by the study, as many investments (e.g. interfaces) are fixed, irrespective of sales volume. This will also impact upon the survival rate of these distributors, as the costs per unit will increase disproportionately.

Lastly, we do not think that the study has even realised that many 'retailers' also fall under T&T obligations. Therefore, in the case of other economic operators, the study's usual calculation error margin of factor 10 should be doubled.

Speculations regarding unique identifiers generated by the manufacturers

The study has based all evaluations and conclusions of the suggested T&T options on ill-designed self-postulated assumptions such as: “unique identifiers ... [are] a key risk for a tobacco control regime” whilst “solution components that are considered lower risk such as recording distribution chain events from manufacture to last point prior to retail are operated by industry“ (both quotations on p.197).

It is self-evident that the purpose of T&T systems is to recreate the journey of legal products through the legal supply chain to identify the last legal transaction before the products entered illicit trade (“the point of diversion”): see Art 1(14) and Art 8(4.1) of the FCTC Protocol. Therefore, the identification of the customer (subsequent economic operator) is the purpose of all T&T systems (for any product). The unique identifier is only a technical enabler. It is obvious that the study diverts attention to irrelevant issues to promote certain restrictions and subsequently promote monopolistic solutions.

Consequently, in its executive summary, the study makes discrediting statements such as “Are shared industry software and systems free from vulnerabilities that may compromise integrity?” and downgrades option 1 in its (highly questionable) CSF tables. First of all, the four manufacturers (and some others) share only very few components and the implemented systems are tailored to individual requirements, to reflect different equipment, technology and IT infrastructure. Please note that all four manufacturers also use SAP systems for accounting, invoicing, stock accounting and excise administration and there have so far been no claims that these should be operated by an “independent” third party.

The main speculation indicates that under option 1: “non-compliant manufacturers have the means to reproduce unique identifiers (as well as the corresponding aggregation relationships) onto undeclared tobacco products for diversion into the parallel illicit distribution chain”. This speculative conclusion is based on the assumption that the unique identifier would be the only tool to verify the quantity declared as released for consumption. This is not the case in 23 MS which use fiscal markings, and we are not aware any problems with legal manufacturers under-declaring the amounts released for consumption in the remaining MS. We also question the hypothesis that the T&T system would be the right tool to address such an imaginary challenge; the majority of illicit products are duty-paid in one country and smuggled into another.

The speculation goes on to assume that packaging lines would be able to recreate the ‘corresponding aggregation’. The statement is contradictory in itself, as it refers to ‘parallel distribution chain’. If replicated identifiers would be found somewhere different to where they should be according to the T&T data of original identifiers (in a parallel illicit distribution chain), this would be clear evidence that the manufacturer is cheating the system. Subsequently, the copied identifiers (including corresponding aggregation) would have to be distributed in the corresponding supply chain, and all operators would have to report each unit only once. Such a complex operation would require criminal intent of all the operators involved in the supply chain – in our view, this is an extremely unlikely scenario. It is conceivable that the study realised that security features are not of much value, as it would be otherwise highly contradictory to suggest “modern tax stamps” and at the same time assume that manufacturers could illegally produce undeclared volume with copied identifiers that have to carry security features. An alternative explanation is that these speculations and accusations were instead set out to support other, commercial, objectives.

If it were accepted that the running such a criminal operation were even feasible - despite the challenges just described – our proposal to use fingerprint technology, printed on the pack, as a security feature would completely exclude any such alleged replication of identifiers, as the identifier has to match the fingerprint (fibre structure) of the pack. An identifier matching the fibre structure of one pack could not obviously match fibre structure of another pack, and any matching identifier would have to be in the database. There is simply no way to bypass this test.

Lastly, we have some reservations about the “key success factors” outlined in the study and the evaluation of the options. The only option compliant with all requirements of Art 15 (option 1) was marked amber regarding factors 4 (p.158) and 9 (p.159), based on a purely speculative interpretation of the Directive and on the unsubstantiated accusations addressed above. However, the non-existent 28 national systems in options 3 and 4 passed the compatibility test (factor 5) and all non-existent options, including option 2, passed the test on minimisation of impact on manufacturing (factor 9) and trade (factor 11). The most basic critical success factors of a balanced and professional feasibility study: such as “compliant with applicable legislation” or “realistic implementation within the adopted timeline” were not even included.

The authors of the study admit on several occasions that there are significant feasibility issues regarding options 2, 3 and 4, however, but these are not considered in the conclusions and recommendations. On the contrary, they are presented as the winning solutions which tick all the boxes. This approach clearly demonstrates the efforts made to discredit all T&T systems developed by individual manufacturers, and serves as a justification to promote the solutions of ‘independent’ third parties.

Security features

We do not wish to reiterate all analysis provided under the previous section on security features, and will therefore only highlight some general conclusions.

We understand that the role of the security feature is to authenticate the products (i.e to identify counterfeit) for consumers and authorities. As stated in previous parts of our submission, counterfeit makes up around 0.6% of EU cigarette consumption (this figure is far less or even non-existent for other product categories). Since counterfeiters regularly fake non-EU stamps to justify the 50% street price discount, we would not expect any impact on counterfeit sales.

The study takes a very confusing approach: It rightly states that 23 Member States already use affixed paper stamps for fiscal purposes. This means that the only impact of the four proposed security feature options, all representing 'modern tax stamps', would only apply to the remaining 5 MS (and perhaps to sell some more expensive stamps to the first group of MS).

The objective of Art 16 is inarguably to authenticate the product. For fiscal purposes, it is more or less irrelevant whether or not a product is genuine or counterfeit, as the focus is on the question of whether excise has been paid. From that perspective, a genuine stamp on a counterfeit product provides evidence fitting the fiscal purpose. However, for authentication of products itself, different measures are required, and from that perspective all four options presented by the study are misguided, and would simply serve to duplicate the existing fiscal stamps without adding any product authentication evidence. Therefore, there is a need for clarification of the role of the security feature.

The only option which provides evidence of authenticity could be developed from elements of option 3, as this is the only option including the characteristics of the product itself: the fibre structure (signature, fingerprint) of the pack. However, the study goes on to draw flawed conclusions. First of all, if the fibre structure of a part of the surface of the pack is digitalised and included in the unique identifier, there is no need for any storage of that fingerprint in any database, as these two elements have to correspond. A copied identifier on a counterfeit pack would not match the fibre structure. The conclusion of the study that:

“using a method of storing the result on the item [in the identifier], in the event the finger printing algorithm is compromised, authorities would not receive any indication that there are illicit products on the internal market that incorrectly would be authenticated as legitimate”
(p.255)

is simply incorrect, as the pack and identifier would match, but this illegally generated identifier would not be in the database of legitimate identifiers. This incorrect conclusion is subsequently used as justification to suggest an additional paper stamp, even under option 3.

In fact, there is no need for any additional paper stamps for authentication. There are three visible elements: the pack itself, the machine and the human readable identifiers. The fingerprint encrypted in the identifier serves as the invisible element of the security feature. In MS which prefer to use fiscal stamps, these provide additional supportive authentication elements, as they are linked to the stamp, but not to the product, as explained above.

The supposed disadvantages of option 3 (stated on p.256) apply in exactly the same way to any other option, and are therefore not exclusive to the fingerprint solution. However, in order to address these issues, alternative authentication solutions should be considered as well. Whilst the fingerprint technology is the most sophisticated, other invisible security features to authenticate the product are widely available and easier to apply: invisible inks, taggants on the pack, tear tape and/or cellophane. The key characteristic shared by these technologies is that they authenticate the products rather than the paper attached to it. On a separate note, taking into account that Art 16 calls for printed or affixed security features with visible and invisible security elements, the focus of the study on purely affixed solutions renders it one-sided. Finally, Art 16 refers to visible and invisible security elements. Instead of following adopted legislation, the study sought to invent "modern tax stamps" with overt, semi-covert, covered and forensic elements, and created a list of critical success factors which to large extent do not reflect Art 16.