

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 (CHAFAEA) 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.f. If other, please specify**

Text of 1 to 800 characters will be accepted

ESTA represents the interests of the European manufacturers, distributors and importers of fine-cut (rolling) tobacco, pipe tobacco, traditional chewing tobacco and nasal snuff tobacco.

The members of ESTA are mainly small, usually family-owned, traditional, businesses and include national associations from the European Union, the accession countries and the European Economic Area.

***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

ESTA
European Smoking Tobacco Association
Rondpoint Schumanplein 9 - Box 1
1040 Brussels
Tel 0032.2.230.80.92
Email:info@esta.be

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

Yes No

***A.3.1. Please enter your registration number in the Transparency Register**

EC Reg. No: 0138855852-93

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

• bf418af8-a492-4830-ae6a-871cd5061711/01 01 2015 ESTA preamble + statutes - update March 2014 -0 November 2014.doc

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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 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 type="radio"/>	<input checked="" 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 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>

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

- **667490c5-4b18-4495-a34d-bcaf03949010/ESTA comments on question B.1.5.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 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.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 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.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 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.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 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.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

- **db54b58d-204b-4114-92a3-50f32a7ee674/ESTA comments on question B.2.5.docx**

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)

• 50ea5d64-da88-4faa-a661-45803d3b3fc5/ESTA comments on question C.1..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

Standardization on the EU level initiated by an entity such as GS1.

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)

*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

The most widely used data carriers in the supply chain which require the least amount of change or modification to existing equipment, or new equipment.

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

Text of 1 to 800 characters will be accepted

The most widely used data carriers in the supply chain which require the least amount of change or modification to existing equipment, or new equipment

***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)

- **1b2f29c9-f467-44e7-81f8-af563fb39b37/ESTA comments on question D.7..docx**

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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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 type="radio"/>	<input type="radio"/>	<input checked="" 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

Pipe tobacco and fine-cut tobacco pouches are produced in small volumes and in a large variety of models, sizes and brands. As a result, production runs are small. Manufacturers require as much flexibility as possible in order to be able to choose the best solution depending on the type of packaging and production volume.

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)

*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.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

Primarily cost considerations, thereby removing the need for investment in expensive decoding equipment.

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

• **9044b087-03d2-4cc6-a89c-b34aa6455c00/ESTA comments on question D.17.docx**

Contact

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



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]



[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



MEMBERS

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



GENERAL ASSEMBLY

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



ADMINISTRATION

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

FINANCE

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



MISCELLANEOUS

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Attachment B.1.5

ESTA comments on question B.1.5.

General remarks

- *On illicit trade*

The illicit trade in fine-cut tobacco and other tobacco products (OTPs) is negligible. As illicit trading is largely conducted by individual consumers, Track and Trace measures will not provide effective counter-measures. Instead it can be better addressed by improved enforcement and cross-border sales regulations.

- *Administrative/financial burden of the Track and Trace measures on small scale manufacturers*

ESTA considers the administrative/financial burden for manufacturers of RYO and OTPs to be 'inappropriate' in all 4 options.

ESTA is concerned about the scope of the measures, which require Track & Trace to be implemented from manufacture to the "last economic operator before the first retail outlet". This will require independent wholesalers to invest in machinery and staff to input data on all tobacco products. Such investment may be justified for high volume mainstream tobacco products, but is highly unlikely to prove cost-effective when applied to small, specialist categories and brands. ESTA fears that the system will discriminate against its members, which are mostly small operators.

- *Necessity to recognize the small scale manufacturers and distributors*

From ESTA's perspective the overriding principle of any Track and Trace measures applied to RYO and OTPs is that they should recognize the small scale manufacturers and distributors. The vast majority of RYO and OTP manufacturers are not large multi-national corporations. Instead they are comparatively small, usually family-owned, traditional, businesses. The distributors of these products in the markets across Europe are virtually all SMEs and in some cases micro-businesses, which will only be in a position to comply with the measures if they are simple and inexpensive to implement. For these operators, many of whom have very limited technical knowledge and capability, a uniform approach across different tobacco categories is inappropriate because it will have a burdensome and disproportionate impact on them.

Option 1

ESTA considers option 1, with direct marking on the production lines carried out by tobacco manufacturers, as being the only option which is compliant with existing legislation, capable of being implemented on time and is technically feasible. This is the only solution endorsed by authorities across the EU, including OLAF. 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 of the Feasibility Study) as individual manufacturers can maintain their own master data (for products and customers).

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/master case), for aggregation data and reporting of events (movements/sales).

Attachment B.2.5

ESTA comments on question B.2.5.

From the 4 options, 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.

Attachment C.1.1

ESTA comments on question C.1

ESTA disagrees with the 'Benefit Analysis' presented in section 11.3.1 of the Feasibility Study (Pages 273-277). According to this paragraph, 'the four solution options for both traceability and security features are designed to address most of the issues identified in the problem statement'. The exact size of the illicit market is unknown, and a number of assumptions are made as to the relative benefits of each Option against a hypothetical figure. This is not compelling justification for the inclusion of RYO and OTPs, for which the illicit trade is negligible, yet whose operators will be subjected to increased costs and complexity. This is not an example of Better Regulation, and in ESTA's view is unreasonable and unacceptable. In ESTA's view the impact of the traceability and security feature requirements should be assessed following the Commission's Better Regulation Agenda, on the basis of which impact assessments are conducted throughout the legislative process, not just when the Commission prepares its proposal. An ad hoc and independent technical panel should be set and should analyse (i) the practicability of implementing Articles 15 and 16, and (ii) whether the costs of doing so will be disproportionate.

Attachment D.7

ESTA comments on question D.7.

The manufacturing process for RYO, pipe tobacco and traditional nasal snuff never takes place on a continuous basis from raw tobacco and packaging materials to the finished product. There is always an interval between the manufacture of the tobacco product and the time when it is placed in its packaging. In most cases further intervals occur between their initial packaging and the point at which the packs are sealed and country-specific health warnings including, where applicable, EAN-codes and tax stamps are applied. It is not uncommon for these processes to take place at different locations and even in different countries.

The principle behind these procedures is that the tobacco for such specialist products has to be moistened before the manufacturing process and that, after they are made, they require carefully controlled drying. As a general rule, the drying process takes a minimum of one week, but it can continue for several months.

ESTA proposes to define the “date and place of manufacture” for these categories of tobacco products as the moment when the goods are in their final packs with the health warning labels, tax stamp and EAN-code labels placed as appropriate. The unique identifier would then be placed on the pack at that moment in time.

ESTA comments on question D.17.

Additional comments on the timing

Companies manufacturing roll-your-own tobacco have to comply by 20 May 2019 with the traceability and security feature requirements (Art. 15 and Art.16). These requirements have not even been drafted yet by the European Commission and additional legislation would be needed at national level. Moreover, the European Commission plans to adopt the Implementing Acts related to Art. 15 and Art.16 during Q2 2017¹. This means that companies will have only two years to make their manufacturing system compliant with TPD2 requirements. This is, especially for small scale manufacturers and distributors, an almost impossible challenge to adapt in such a short period of time.

¹ European Commission TPD2 Indicative Implementation Plan:
http://ec.europa.eu/health/tobacco/docs/implementation_plan_en.pdf