

## 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](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](mailto: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

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### \*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*

Spanish National Dental Association (Consejo General de Dentistas de España)

- \*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*

Consejo general de Dentistas de España  
Calle Alcalá 79, 2º  
Madrid 28009  
Spain

- \*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.

• **151d5db2-8f94-44f2-8f3f-c6cfaada3d3f/RD2828-1998 consolidado.pdf**

## B. Options proposed in the Feasibility Study

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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 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 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.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 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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 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 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 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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)

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

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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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>

## D. Additional questions

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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.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*

Wepreferred data carrier would be a 2D barcodes (also known as QR codes or data matrix codes) because:

- They have been used in other industry such as the pharmaceuticals, food, alcohol and parcel delivery services;
- They are cheap to make and easy to generate;
- They can be used to link to a wide variety of types of information;
- They are internationally standardised;
- They can quickly be

\*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 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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Aggregation of products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

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.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.a. If yes, please explain your considerations

*Text of 1 to 800 characters will be accepted*

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](mailto:SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu)

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