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 (CHAFEA) 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.c. Please specify:

- i) Provider of solutions for tracking and tracing systems (or parts thereof)
- ii) Provider of solutions for security features (or parts thereof)
- iii) Data Management Providers (or parts thereof)

*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

Hologram. Industries
Parc d'Activités Gustave Eiffel – Bussy Saint Georges
77607 Marne la Vallée Cedex 3
France
[redacted]
[redacted]

*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.

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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	○	◉	○	○	○	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	◉	○	○	○	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	◉	○	○
* Administrative/financial burden for economic operators	◉	○	○	○	○	○
* Administrative/financial burden for public authorities	○	○	○	○	◉	○

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	○	◉	○	○	○	○
*Interoperability	○	◉	○	○	○	○
*Ease of operation for users	○	○	○	◉	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	○	◉	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	◉	○	○	○	○

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	○	◉	○	○	○	○
*Interoperability	○	○	◉	○	○	○
*Ease of operation for users	○	○	○	◉	○	○
*System integrity (e.g. low risk of manipulation)	○	○	○	◉	○	○
*Potential of reducing illicit trade	○	○	○	◉	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	○	◉	○	○	○

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	○	○	◉	○	○	○
*Interoperability	○	◉	○	○	○	○
*Ease of operation for users	○	○	◉	○	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	◉	○	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	◉	○	○	○	○	○

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

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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	◉	○	○	○	○	○
*Interoperability	◉	○	○	○	○	○
*Ease of operation for users	○	○	◉	○	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	◉	○	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	◉	○	○	○	○

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	○	◉	○	○	○	○
*Interoperability	○	○	◉	○	○	○
*Ease of operation for users	○	○	○	◉	○	○
*System integrity (e.g. low risk of manipulation)	○	◉	○	○	○	○
*Potential of reducing illicit trade	○	◉	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	◉	○	○	○	○

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	○	○	○	◉	○	○
*Interoperability	○	○	○	◉	○	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	◉	○	○	○	○
*Potential of reducing illicit trade	○	○	◉	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	○	○	◉	○	○

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	◉	○	○	○	○	○
*Interoperability	◉	○	○	○	○	○
*Ease of operation for users	○	○	○	◉	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	◉	○	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	◉	○	○	○	○

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	○	○	◉	○	○	○
*The cost analysis presented in section 11.3.2 of the Feasibility Study	○	○	◉	○	○	○

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)?

- [x] a) A single standard provided by a relevant standardization body
- [x] 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

We do believe that GS1 is a good basis for discussion, considering GS1 is a wordlwide standard already well established in our industry. GS1 is also providing a standard easily scallable on the considered market

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)?

- [x] a) Solution based on a single data carrier (e.g. 1D or 2D data carriers)
- [x] 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

Considering the need for interoperatbility and integration cost a standard data carrier as a 2D carrier sounds to us the best option to implement for integration and cost concerns.

*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;
- [x] 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)

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*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;
- [x] 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	○	◉	○	○	○
*Marking products with serialized unique identifiers on the production line	○	◉	○	○	○
*Verifying if products are properly marked on the production line	◉	○	○	○	○
*Scanning products upon dispatch from manufacturer's/importer's warehouse	◉	○	○	○	○
*Scanning products upon receipt at distributor's/wholesaler's premises	◉	○	○	○	○

*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

Considering a security system based on B.2.1, such solution will be based on an authentication technology similar to a modern tax stamp. This solution is implying that a known number of tax stamps are delivered to the tobacco manufacturer for application during production.

Such system will imply strong security measures concerning the distribution of tax stamps:

1. Securely monitor the different solution flows – what was sent to whom in which quantities…
2. Precise stock control with adequate security measures – limited and secured access to the stocks…
3. Precise control of solution status – activated when applied, deactivated if stolen or destroyed during application…

This security measures should be recommended by the solution provider and adapted to operators (but still enforcing a sufficient level of security constraints).

*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)?

- [x] a) A security feature is affixed;
- [x] 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/puch/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;
- [x] 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)?

- [x] 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)

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*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

A system that could be used by individual consumers will reach much higher level of control than any systems relying solely on customs or official experts. Such system will provide higher control rate, higher market coverage and market knowledge about the systems, which will logically provide a much higher system efficiency and potential project ROI.
Even if individual consumers will not have the same level of expertise than professional an ergonomic and automated authentication application will provide sufficient level of expertise for large public authentication and will raise drastically consumer awareness about the implemented solutions.

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

[redacted]

Attachment A4

[redacted]

[redacted]

[redacted]

Le varietur n°. XB1507075 - 30/07/2015

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Attachment B.1.5

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

As described in the initial study it is doubtful that a system operated by Tobacco manufacturer can be of any interest to diminish the level of diversion as it is assumed that Tobacco manufacturer were or are still implied in the products regular leaks into parallel trades.

According to the provided analysis we do agree that a system decided by each member state may lead to impossible interoperability and important economic burden for operators.

Attachment D.5

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)

We consider that the chosen system should operate both machine and human readable codes for two main reasons:

1. Codes can be damages along the production and distribution chain even if redundant; a human readable code is a security back-up that should be implemented for any machine readable codes with such wide implementation objectives.
2. It is clearly expressed in the initial study that this system should be usable by all stakeholders therefor limiting the system to machine readable codes will exclude all user not having dedicated access to a specific reader and corresponding network connection. A system combining both types of codes seems to be the most secured and efficient solution for such systems.

Attachment D.15

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

Such reporting and query tools are directly impacted by the level of expertise and knowledge about the possibilities of the security solution and by the understanding of the data collected by the systems. Defining precisely the reporting and query tools possibilities is therefor much easier and will certainly be much more efficient if provided by the provider of data collection between the manufacturing and distribution chain.