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.a. Please specify:

- [x] i) Cigarettes
- [x] ii) RYO
- [x] iii) Cigarillos
- [x] iv) Cigars
- [x] v) Pipe tobacco
- [x] vi) Water pipe tobacco
- [ ] vii) Smokeless tobacco including chewing, oral and nasal tobacco
- [ ] viii) 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

Cimabel vzw/asbl
Cigarette Manufacturers of Belgium and Luxemburg

[redacted]
Secretary general
Terhulpsesteenweg 189
1170 Brussel

+32 471 89 00 84
secretariat@cimabel.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

94376854542-25

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

- **841890a4-faaf-4bf6-bdac-bf3374c47cb5/TradeRegistry Cimabel.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	◉	○	○	○	○	○
*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)

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
- [ ] b) A public accreditation or similar system based on the minimum technical and interoperability requirements that allow for the parallel use of several standards;
- [x] 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: 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, which combines Product Authentication and Track&Trace technologies. Codentify generates a unique number to serialise the consumer unit. Each Codentify code is a unique, unpredictable set of 12 letters or numbers readable by the naked eye. 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: the DotCode.

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;
- [x] c) Another solution;
- [ ] d) No opinion

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

Text of 1 to 800 characters will be accepted

> For the lowest packaging unit (e.g. pack of cigarettes, pouch) 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', GS1 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;
- [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)

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

- [x] 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

*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;
- [x] c) A security feature is printed;
- [x] d) A security feature is put on the pack/tin/puch/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)

*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;
- [x] b) Provider of data storage services;
- [x] c) Another entity
- [ ] d) No opinion

*D.14.c. Please explain

Text of 1 to 800 characters will be accepted

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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

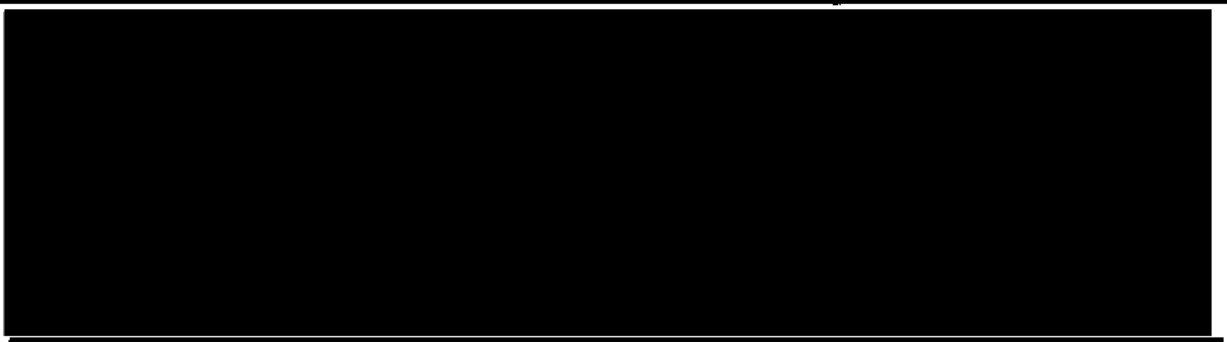
Attachment A4 -

[redacted]

[redacted]

[redacted]

[redacted]



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