

## 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.d. Please specify:

- i) National government
- ii) 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*

Ministry of Health and Elderly  
Holbergsgade 6  
DK-1057 Copenhagen K  
sum@sum.dk

Ministry of Taxation  
Nicolai Eigtveds Gade 28  
DK-1402 Copenhagen K  
skm@skm.dk

## 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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.1.2. 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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.1.3. 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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.1.4. 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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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)

- **eadba450-41af-4f3b-8e79-2985822eaa39/Additional comments - B.1.5 and B.2.5.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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.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 checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input 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.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

- [a3e361e6-5c7b-41e0-af4d-2fb9a11c43a3/Additional comments - B.1.5 and B.2.5.docx](#)

## 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 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)

• [8ee0b851-ac6d-4f8a-ac14-4235ec57047d/Main reasons for disagreement.docx](#)

## 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.1.a. Please indicate your preferred standardization body

*Text of 1 to 400 characters will be accepted*

The use of a single standard should not be ruled out per se. No preferred standardization body.

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.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)

- **5e2121c4-f832-4aa2-99f0-296b440315fa/Additional comments - 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	<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 checked="" type="radio"/>	<input type="radio"/>	<input 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*

Economic operator is understood as the tobacco industry during production and when leaving the production facility. Later in the distribution chain the term is understood to cover the distributor/wholesaler.

In order to avoid excessive administrative burdens for the economic operators and given that the appropriate authority supervision and control are in place it should not be excluded that the industry can take part in the implementation of the Tobacco Product Directive.

\*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/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*

It should be born in mind that the relevant production lines do not solely send out cigarettes and the like (wrapped in cellophane), but will eventually also be small batches of much diversified types of tobacco products (both when looking at the type and the size of the packaging, but also when assessing the potential for counterfeiting, smuggling etc.).

The national authorities should be given the possibility of allowing the use of "stickers" on small batches of other types of tobacco products.

The considerations on combining e.g. the unique identifier in the track and trace system, the security feature and existing fiscal stamps should be part of an exercise of finding the least burdensome way of implementing the TPD.

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.12.c. Please explain your other solution

*Text of 1 to 800 characters will be accepted*

Easy access to the data for the national authorities should be taken into account as well as data protection and protection of business secrecy.

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.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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## Attachment B.1.5

The choice has fallen on the category “neutral” due to lack of detailed information on each option – the impact will to a large extent depend on how the actual implementation is going to be performed. Based on the feasibility study it has not been possible to evaluate each option’s technical feasibility, interoperability, ease of operation for users, system integrity, potential of reducing illicit trade and administrative/financial burden for economic operators and for the public authorities. Some principles that should be guidelines for the future work on the measures, can however be identified:

- Finding the least burdensome way of implementing the Tobacco Product Directive (TPD) for both business and administration lies as an overall objective.
- Avoidance of distortion of the competition in the market should also be part of the overall aim.
- An open source solution with access to the underlying readable code should be the starting point in order not to create a monopolistic or oligopolistic market for solution providers.
- An accreditation system should ensure a certain minimum level in all EU Member States in order not to hinder the free movements of goods – and in general in order not to contravene the free movements.
- A common EU standard could be considered if decisions on whom and what terms are left to the national authorities.
- An accreditation system should be applicable to *all* types of tobacco production, i.e. the use of the same scanning equipment and IT system in the distribution chain no matter the type of tobacco product. If different requirements were imposed depending on the type of tobacco products the risk would be that the wholesalers would discard themselves of the less demanded types of tobacco products due to the extra hassle or different requirements in handling these products.
- An accreditation system should be sufficiently detailed to ensure compatibility and interoperability across borders, but not so detailed that only a few solution providers actually will be able to live up to the requirements.
- It should be born in mind that the relevant production lines do not solely send out cigarettes and the like (wrapped in cellophane), but will eventually also be small batches of much diversified types of tobacco products (both when looking at the type and the size of the packaging, but also when assessing the potential for counterfeiting, smuggling etc.).
- Some leeway should be given to the national authorities when implementing the practical requirements – in order not to overburden small and medium sized companies with niche production of other types of tobacco products. Examples could be to give the national authorities the possibility of allowing the use of “stickers” on small batches of other types of tobacco products and let the national authorities determine the precise requirements for the location of this “sticker” on the same type of products.
- The considerations on combining e.g. the unique identifier in the track and trace system, the security feature and existing fiscal stamps should be part of an exercise of finding the least burdensome way of implementing the TPD.
- Economic operators involved in the tobacco trade should not be excluded from taking part in the implementation of the TPD – given that the appropriate authority supervision and control are in place.

## Attachment B.2.5

The choice has fallen on the category “neutral” due to lack of detailed information on each option – the impact will to a large extent depend on how the actual implementation is going to be performed. Based on the feasibility study it has not been possible to evaluate each option’s technical feasibility, interoperability, ease of operation for users, system integrity, potential of reducing illicit trade and administrative/financial burden for economic operators and for the public authorities. Some principles that should be guidelines for the future work on the measures, can however be identified:

- Finding the least burdensome way of implementing the Tobacco Product Directive (TPD) for both business and administration lies as an overall objective.
- Avoidance of distortion of the competition in the market should also be part of the overall aim.
- An open source solution with access to the underlying readable code should be the starting point in order not to create a monopolistic or oligopolistic market for solution providers.
- An accreditation system should ensure a certain minimum level in all EU Member States in order not to hinder the free movements of goods – and in general in order not to contravene the free movements.
- A common EU standard could be considered if decisions on whom and what terms are left to the national authorities.
- An accreditation system should be applicable to *all* types of tobacco production, i.e. the use of the same scanning equipment and IT system in the distribution chain no matter the type of tobacco product. If different requirements were imposed depending on the type of tobacco products the risk would be that the wholesalers would discard themselves of the less demanded types of tobacco products due to the extra hassle or different requirements in handling these products.
- An accreditation system should be sufficiently detailed to ensure compatibility and interoperability across borders, but not so detailed that only a few solution providers actually will be able to live up to the requirements.
- It should be born in mind that the relevant production lines do not solely send out cigarettes and the like (wrapped in cellophane), but will eventually also be small batches of much diversified types of tobacco products (both when looking at the type and the size of the packaging, but also when assessing the potential for counterfeiting, smuggling etc.).
- Some leeway should be given to the national authorities when implementing the practical requirements – in order not to overburden small and medium sized companies with niche production of other types of tobacco products. Examples could be to give the national authorities the possibility of allowing the use of “stickers” on small batches of other types of tobacco products and let the national authorities determine the precise requirements for the location of this “sticker” on the same type of products.
- The considerations on combining e.g. the unique identifier in the track and trace system, the security feature and existing fiscal stamps should be part of an exercise of finding the least burdensome way of implementing the TPD.
- Economic operators involved in the tobacco trade should not be excluded from taking part in the implementation of the TPD – given that the appropriate authority supervision and control are in place.

## Attachment C.1.1

The cost-benefit analysis is not entirely convincing both in terms of calculation basis and that not all relevant parameters (in the industry and the distribution chain) seemed to have been taken into account when the assessment of costs associated with the implementation were done.



## Attachment D.7

Some leeway should be given to the national authorities when implementing the practical requirements – in order not to overburden small and medium sized companies with niche production of other types of tobacco products. Examples could be to give the national authorities the possibility of allowing the use of “stickers” on small batches of other types of tobacco products and let the national authorities determine the precise requirements for the location of this “sticker” on the same type of products.

For the niche production of other types of tobacco products the understanding is that the only solution that can be implemented in practical terms is b) After a pack/tin/pouch/item is folded/assembled and filled with products.