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
- O d) Governmental organisation
- 🔘 e) NGO
- f) Other

*A.1.f. If other, please specify

Text of 1 to 800 characters will be accepted

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The Tobacco Manufacturers' Association (TMA) is the trade association
for tobacco companies that operate in the UK. It is funded by its three
member companies: British American Tobacco UK Ltd, Gallaher Ltd (a
member of the Japan Tobacco International group) and Imperial Tobacco
Ltd. http://www.the-tma.org.uk/
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*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

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The Tobacco Manufacturers' Association
14-16 Burwood House
Caxton Street
London
SW1H 0QT
United Kingdom
info@the-tma.org.uk
00 44 207 544 0100
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*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	۲	0	0	0	0	O
*Interoperability	۲	0	0	0	O	0
*Ease of operation for users	۲	\odot	O	0	O	O
*System integrity (e.g. low risk of manipulation)	۲		0	0	0	0
*Potential of reducing illicit trade	۲	0	0	0	0	O
* Administrative/financial burden for economic operators	۲		۲	0	0	0
* Administrative/financial burden for public authorities	۲		0	0	۲	0

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	0	0	O	0	۲	0
*Interoperability	O	0	O	0	۲	0
*Ease of operation for users	O	0	0	O	۲	O
*System integrity (e.g. low risk of manipulation)	0	©	0	O	۲	O
*Potential of reducing illicit trade	0	0	0	O	۲	O
* Administrative/financial burden for economic operators	0	0	0	0	۲	0
* Administrative/financial burden for public authorities	0	0	0	0	۲	0

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	0	0	0	0	۲	O
*Interoperability	0	0	O	O	۲	O
*Ease of operation for users	0	0	O	0	۲	O
*System integrity (e.g. low risk of manipulation)	0	©	O	O	۲	0
*Potential of reducing illicit trade	0	0	0	0	۲	0
* Administrative/financial burden for economic operators	0	0	0	0	۲	۲
* Administrative/financial burden for public authorities	0	©	0	©	۲	0

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	0	0	0	0	۲	O
*Interoperability	0	0	0	0	۲	O
*Ease of operation for users	0	0	۲	0	۲	۲
*System integrity (e.g. low risk of manipulation)	0	0	0	0	۲	0
*Potential of reducing illicit trade	0	0	0	0	۲	0
* Administrative/financial burden for economic operators	0	0	0	0	۲	0
* Administrative/financial burden for public authorities	0	© © @		۲	0	

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	0	0	0	0	۲	O
*Interoperability	0	0	O	0	۲	O
*Ease of operation for users	0	0	0	0	۲	۲
*System integrity (e.g. low risk of manipulation)	0		0	O	۲	0
*Potential of reducing illicit trade	0	0	0	0	۲	O
* Administrative/financial burden for economic operators	0	0	O	0	۲	0
* Administrative/financial burden for public authorities	0		0	0	۲	0

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	0	0	0	0	۲	0
*Interoperability	0	0	0	0	۲	
*Ease of operation for users	0	Image: Constraint of the second sec		۲	O	
*System integrity (e.g. low risk of manipulation)	0	©	0	0	۲	O
*Potential of reducing illicit trade	0	0	0	0	۲	O
* Administrative/financial burden for economic operators	0	0	۲	0	۲	O
* Administrative/financial burden for public authorities	0	©	0	0	۲	0

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	0	۲	O	0	0	0
*Interoperability	0	۲	O	0	0	O
*Ease of operation for users	0	۲	0	0	0	0
*System integrity (e.g. low risk of manipulation)	0	۲	0	0	0	0
*Potential of reducing illicit trade	۲	۲	0	0	0	0
* Administrative/financial burden for economic operators	0	۲	O	0	0	0
* Administrative/financial burden for public authorities	0	۲	0	0	0	0

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	0	0	0	0	۲	0
*Interoperability	0	0	0	0	۲	O
*Ease of operation for users	0	0	0	0	۲	O
*System integrity (e.g. low risk of manipulation)	0	\odot	0	0	۲	0
*Potential of reducing illicit trade	0	0	0	0	۲	0
* Administrative/financial burden for economic operators	0	0	0	0	۲	0
* Administrative/financial burden for public authorities	0	O	0	0	۲	0

- B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)
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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	0	0	©	0	۲	0
*The cost analysis presented in section 11.3.2 of the Feasibility Study	0	O	©	O	۲	©

*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)

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D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16). When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.

*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single standard provided by a relevant standardization body
- b) A public accreditation or similar system based on the minimum technical and
- interoperability requirements that allow for the parallel use of several standards;
- c) Another solution
- d) No opinion

*D.1.a. Please indicate your preferred standardization body

Text of 1 to 400 characters will be accepted

We believe that the GS1 standard data carriers are the most suitable option

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.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

Please refer to TMA member company responses.

*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)

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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	0	O	۲	O	0
*Marking products with serialized unique identifiers on the production line	0	0	۲	0	O
*Verifying if products are properly marked on the production line	0	0	۲	0	O
*Scanning products upon dispatch from manufacturer's/importer's warehouse	0	0	۲	0	٢
*Scanning products upon receipt at distributor's/wholesaler's premises	0	0	۲	O	۲

*Scanning products upon dispatch from distributor's/wholesaler's premises	©	©	۲	©	0
*Aggregation of products	0	0	۲	0	\bigcirc

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;
- Image: 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

As indicated previously, we believe that the security feature options as presented do not encompass the available authentication technologies.

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

Yes, as it provides another layer in checking a product's legitimacy at the point of purchase.

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



The Tobacco Manufacturers' Association (TMA) is the trade association for tobacco companies that operate in the UK. It is funded by its three member companies: British American Tobacco UK Ltd, Gallaher Ltd (a member of the Japan Tobacco International group) and Imperial Tobacco Ltd. http://www.the-tma.org.uk/

Attachmetn B.1.5



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

As the TMA does not have a commercial role, we are not in a position to provide a comprehensive response to the feasibility questionnaire. That said, we would like to provide comment on some of the general points as well providing brief commentary on the UK markets approach to tackling illegal trade, which is pertinent to this process.

With regards to implementation, it is quite clear that timing will be a major issue, particularly in relation to Options 2,3, and 4 of the Feasibility Study. Options 2,3 and 4 will require the development of a new system or appointment of an EU-wide or national provider of a tracking and tracing system or a third party to manage the required database/s. This process would naturally require a public tender that could not take place before the adoption of secondary legislation. This would then have to be implemented, according to the Feasibility Study, in at least 230 manufacturing companies on 745 EU cigarette manufacturing lines. This poses a number of questions around the timelines for those tasked with delivering the solution in addition to the impact on economic operators. Therefore, Option 1 appears to be the only option that complies with existing legislation and is capable of being implemented within the required timeframe.

We would like to reiterate comments made by the Confederation of European Community Cigarette Manufacturers (CECCM) that the legislation should prescribe recognised international open standards and ensure that competition can exist between solution providers (track and trace, security feature, and data storage), which in turn allows all economic operators in charge of implementing Article 15 to choose their preferred supplier/s. This approach mirrors Option 1 of the feasibility study, moreover, this option provides a good basis for further work on the definition of technical standards foreseen in Article 15 of the TPD.

Attachment B.2.5



B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

All four of the options presented in the feasibility study are based on paper markers or 'stamps' which are attached to the packaging. These only provide for securing the stamp rather than the authenticity of the product and none of the options embrace the existence of more advanced and effective authentication technologies.

For example, in the UK, since 2007 cigarette and hand rolling tobacco products manufactured by the 4 largest companies (BAT, ITL, JTI & PMI) have carried covert anti-counterfeit taggant technology. At the March 2007 Budget it was announced that the UK Government had accepted an offer from the TMA's member companies to voluntarily incorporate technology on cigarette packs to allow the easy identification of genuine/counterfeit product in the retail network. Since 1st October 2007 all cigarettes manufactured for the UK market by our member companies and Philip Morris International carry the technology. This was extended to hand rolling tobacco from 1st October 2008. The anti-counterfeiting (reader) device used to detect illicit counterfeit product is being used across the UK by HM Revenue & Customs and Trading Standards Officers. There are several hundred reader devices in circulation and in the 8 years since its inception there have been no reported incidences of the taggant being copied.

We therefore support CECCM's position that an additional option should be considered which would allow member states to choose alternative solutions, and in turn broadening the current and restrictive proposal beyond only security stamp providers for the implementation of Article 16 of the TPD. Regrettably, the feasibility report rather overlooks the type of technologies that have existed very successfully in the UK over the past 8 years.

Attachment C.1.1



C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please

We have some justifiable concerns over the cost benefit analysis (CBA) although this is being addressed in greater detail by our member companies. As a general observation, it is clear that the CBA when looking at Option 1 grossly underestimates the potential cost burden on manufacturers, and given that the CBA for Options 2-4 appear to be based on the costs associated with Option 1, we seriously doubt their credibility too.

The CBA appears to also underestimate the cost burden on other economic operators in the distributive trade, which is perhaps typified by the fact that it is not yet clear whether some retailers will fall under the requirements for tracking and tracing.

Attachment D.7



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)

This would suggest that Option 4 (pre-printed label) would not comply with the Directive, as some of the data required under Art.15.2 of the TPD will not form part of the pre-printed label e.g. the date of manufacture / production shift / time of manufacture. The FCTC also stipulates that the date and location of manufacture has to form part of the unique identification markings. This clearly shows that pre-printed labels do not meet these requirements.