Case Id: 810ea9a5-eb41-4b2d-a1c7-362a9baa4a4e

Date: 31/07/2015 12:12:30

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.f. If other, please specify

Text of 1 to 800 characters will be accepted

SWA is the official trade association for Scotland's food and drink wholesaling business. Our members are engaged in the supply of legal tobacco products. We are supportive of measures to track and trace tobacco products and to improve security. We have wholesale members who operate depots and cash and carrys supplying to a range of outlets including convenience stores and licensed premises. Some members own retail outlets. We also have supplier members including tobacco manufacturers.

*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

Scottish Wholesale Association 30 McDonald Pl, Edinburgh, Midlothian EH7 4NH +44 131 556 8753

http://www.scottishwholesale.co.uk/

- *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.
 - · 0b0ea952-ea15-4ade-a6d7-0ce8740db7a1/Section A4.doc

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

- B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
 - 258ff77f-342f-48ce-a992-d233d0ccd38d/Section B1.doc
 - 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 | • | 0 |
| *Interoperability | 0 | • | 0 | 0 | • | 0 |
| *Ease of operation for users | 0 | • | 0 | • | • | 0 |
| *System integrity (e.g. low risk of manipulation) | • | • | 0 | • | • | • |
| *Potential of reducing illicit trade | 0 | • | 0 | 0 | • | 0 |
| * Administrative/financial burden for economic operators | 0 | • | 0 | • | • | 0 |
| * Administrative/financial burden for public authorities | 0 | © | 0 | 0 | • | 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 | • | 0 |
| *Interoperability | © | • | 0 | 0 | • | 0 |
| *Ease of operation for users | 0 | • | 0 | • | • | • |
| *System integrity (e.g. low risk of manipulation) | 0 | • | • | • | • | • |
| *Potential of reducing illicit trade | 0 | • | 0 | • | • | 0 |
| * Administrative/financial burden for economic operators | 0 | • | 0 | © | • | • |
| * Administrative/financial burden for public authorities | 0 | • | 0 | • | • | 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 | • | 0 | © | 0 | 0 |
| *Interoperability | 0 | • | 0 | 0 | 0 | 0 |
| *Ease of operation for users | 0 | • | 0 | 0 | 0 | 0 |
| *System integrity (e.g. low risk of manipulation) | 0 | • | • | © | • | 0 |
| *Potential of reducing illicit trade | 0 | • | 0 | • | • | 0 |
| * Administrative/financial burden for economic operators | 0 | • | 0 | • | • | 0 |
| * Administrative/financial burden for public authorities | • | • | 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 | • | 0 |
| *Interoperability | 0 | • | 0 | 0 | • | 0 |
| *Ease of operation for users | 0 | • | 0 | • | • | 0 |
| *System integrity (e.g. low risk of manipulation) | • | • | 0 | • | • | • |
| *Potential of reducing illicit trade | 0 | • | 0 | 0 | • | 0 |
| * Administrative/financial burden for economic operators | 0 | • | 0 | • | • | 0 |
| * Administrative/financial burden for public authorities | 0 | © | 0 | 0 | • | 0 |

- B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)
 - 951b4f49-f92b-45ad-9bda-b5de7fce93eb/Section B2.doc

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 | © | © | • | © | • | © |

- *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)
 - 45f7d705-b701-4451-94fc-f12cf1ae0e3e/Section C1.doc

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 |
| GS1 standard data carriers |
| |
| 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

SWA wish to see a solution which is effective against illicit trade however it's essential this system is affordable to our members.

- *D.4. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?
 - a) System only operating with machine readable codes;
 - b) System operating both with machine and human readable codes;
 - c) No opinion
- D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)
- *D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?
 - a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
 - b) After a pack/tin/pouch/item is folded/assembled and filled with products;
 - c) No opinion
- D.7. Please upload any additional comments relating to the placement of a serialized unique identifier referred to in question D.6. above (max. 2 pages)

D.8. Which entity should be responsible for?

| | Economic operator involved in the tobacco trade without specific supervision | Economic operator involved in the tobacco trade supervised by the third party auditor | Economic operator involved in the tobacco trade supervised by the authorities | Independent third party | No opinion |
|---|--|---|---|----------------------------|---------------|
| *Generating serialized unique identifiers | 0 | 0 | • | 0 | © |
| *Marking products with serialized unique identifiers on the production line | • | • | • | © | 0 |
| *Verifying if products are properly marked on the production line | 0 | • | • | • | © |
| *Scanning products upon dispatch from manufacturer's/importer's warehouse | 0 | • | • | • | 0 |
| *Scanning products upon receipt at distributor's/wholesaler's premises | 0 | • | • | • | 0 |
| | | | | | |

| *Scanning products upon dispatch from distributor's/wholesaler's premises | • | • | • | • | © | |
|--|---|---|---|---|---|--|
| *Aggregation of products | 0 | 0 | • | 0 | 0 | |

| D.9. In relation to question D.8. above, please specify any other measures that your organisatio considers relevant |
|--|
| Text of 1 to 1200 characters will be accepted |
| |
| *D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which of the following solutions do you consider as appropriate (multiple answers possible)? □ a) A security feature is affixed; □ b) A security feature is affixed and integrated with the tax stamps or national identification marks; □ c) A security feature is printed; □ d) A security feature is put on the pack/tin/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 |
| The UK currently doesn't use stamp systems. UK authorities currently make use of a manufacturers identification system - Codentify to identify and authenticate products. We believe this might form the basis for an authentication and track and trace system which might be applied effectively and timeously with minimum expense and disruption to our members. We believe there are also fingerprint systems which may enhance this. |
| 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 the following solutions do you consider as appropriate (multiple answers possible)? a) A single centralised storage for all operators; b) An accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory); c) Another solution d) No opinion |

| | D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages) |
|-----------------------------|---|
| | *D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)? ☑ a) Provider of solutions to collect the data from the manufacturing and distribution chain; ☑ b) Provider of data storage services; ☐ c) Another entity ☐ d) No opinion |
| | D.15. Please upload any additional comments relating to the development of reporting and query tools referred to in question D.14. above (max. 2 pages) |
| | *D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)? a) Yes b) No c) No opinion |
| | D.16.a. If yes, please explain your considerations Text of 1 to 800 characters will be accepted |
| | D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages) |
| Con î ⊠ SÆ | tact ANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu |

Attachment A4

Section A4

Unclear what is required here.

See our website for further information http://www.scottishwholesale.co.uk/

Attachment B.1.5

Section B1

SWA are committed to fighting the illicit trade on tobacco products. This trade has negative impacts on our members and wider civic society as well as on the UK Exchequer. We wish to see the adoption of a track and trace system which is effective and one that is proportionate to the threat. Our members who trade in tobacco currently scan products on their delivery from tobacco manufacturers. This is a time consuming process. They also ensure that they only sell tobacco products on to retailers who are covered by the Scottish Tobacco Retailers Register. Our members require a track and trace system which is easy to understand and to implement. Given the legislative and implementation timetable behind the Tobacco Directive we would suggest Option 1 because we believe an existing manufacturers' system – Codentify- might be able to be utilised for this purpose effectively and timeously. Options 2,3 and 4 require tendering and development which would make the 2019implementation deadline less achievable. The UK authorities e.g HMRC are already using the Codentify system for authentication purposes . We believe therefore Option 1 would mean that authorities and our members would be able to undertake training on this system within a short timeframe.

Attachment B.2.5

Section B2

All 4 options are based on paper markers or stamps which we believe is a retrograde step. We believe that stamps are more easily counterfeited and that paper markers or stamps attached to the product packaging doesn't mean the pack contents are necessarily authentic. We believe the technology already employed by the major UK tobacco manufacturers (Codentify) and currently utilised and supported by the UK Government agencies would be more effective. This has been voluntarily in operation since 2007 on cigarettes and since 2008 on hand rolling tobacco. The current system has been shown to work in practice. We would support the proposal that member states should be able to choose their own specific solution when that solution has already proven to be effective.

Attachment C.1.1

Section C1

UK Tobacco manufacturers currently utilise an effective authentication system. SWA believe that it's extension as a model for track and trace as well as for authentication is likely to be most cost effective to the manufacturing companies and throughout the legal tobacco supply chain. We are currently unable to quantify the real costs to our members.

There does appear to be some confusion around the definition of a retailer and who exactly would be covered by Articles 15 and 16. . There are examples of secondary wholesale i.e "incidental sales" retailer to retailer. The distribution chain doesn't necessarily follow a clear path from tobacco manufacturer to depot to wholesaler to retailer.