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# 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 <a href="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</a>. 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 <a href="https://ec.europa.eu/eusurvey/runner/trace">https://ec.europa.eu/eusurvey/runner/trace</a> 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
O e) NGO
Of) Other
*A.1.b. Please specify:
i) Importer
☑ ii) Distributor
iii) Wholesaler
iv) Warehouse operator (unless part of 1a of 1bi, ii or iii)
v) 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

Naas Vending Services
Naas
Co. Kildare
Republic of Ireland
Tel: +353 (045)888267
Email: info@naasvending.ie

- \*A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):
  - O Yes O No
- \*A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.
  - · da2dec89-71a4-4a17-b32c-72374e3a4002/CompanyRegistartionInformation.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	•	0	0	0	0	0
*Interoperability	•	0	0	0	0	0
*Ease of operation for users	•	©	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
* Administrative/financial burden for public authorities	•	©	0	0	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
*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	•			•	•
*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	

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	•			•	•
*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	

- B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
  - e83c2526-6beb-4d10-ad6f-c33e48ae5026/Article 15.pdf
  - 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	0
*Ease of operation for users	•	©	0	©	0	0
*System integrity (e.g. low risk of manipulation)	•	©	•	0	0	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

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)	•	•	•	•	•	•
*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	•	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	0	•	0	•	•	0
* Administrative/financial burden for public authorities	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	•	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	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)
  - 99f50a7a-79aa-41c0-93ce-e5c5adbcfa31/Article 16.pdf

# 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)
  - 044b0b54-ab77-41c2-9bbd-12530e489f57/Calculations of cost.pdf

# 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.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	0	•
*Marking products with serialized unique identifiers on the production line	•	•	•	•	•
*Verifying if products are properly marked on the production line	0	•	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	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 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;
<ul><li>d) A security feature is put on the pack/tin/puch/item through a different method;</li></ul>
☑ e) No opinion
D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)
*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which of the following solutions do you consider as appropriate (multiple answers possible)?   □ a) A single centralised storage for all operators;
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
  - O 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

# Attachment A4

Sean Dunne Vending Company Limited

Company Registration Number – 469519

Registered Office – 1 Terenure Place, Terenure, Dublin 6W

Business Address – Unit J7, M7 Business Park, Newhall, Naas, Kildare, Ireland

### Attachment B.1.5

### Article 15

The Report provides four T&T options. Option 1 of the report, which our organisation is supportive of, envisages a T&T solution fulfilling the following criteria in line with TPD:

- Government can control and audit T&T;
- Interoperable, based on internationally recognised open standards, encouraging competition;
- Embedded in the manufacturing process allowing information to be included in the unique identifier itself as requested by TPD.

Options 2, 3 and 4 would require significant changes of Art 15, in particular of recital 31 and paragraphs 7 and 8, and would grant additional power to the Commission and/or Member States to select an EU-wide or national monopolistic provider. Any future change of the provider would require significant investment and almost impossible implementation time, therefore an indefinite EU-wide or national monopolistic situation would be *de facto* granted.

In addition to this, Options 2, 3, and 4 recommend the appointment of a service provider by Member State and/or EU which is against the TPD legislation and most probably EU competition law as well.

### These options;

- Go beyond the TPD legislation with a monopolistic approach imposed by the Member State or the Commission on manufacturers, importers, distributors and wholesalers, however apparently not paid for by them;
- Provide no flexibility in solution provider;
- Separate National databases would be inconsistent with the EU single market as it would be very difficult to track products in their journey throughout the EU;
- There would be a huge administrative burden and cost with wide scale disruption to the tobacco supply chain;
- Not adaptable to all current manufacturing processes;

### Attachment B.2.5

### Article 16

The four options are based on paper markers attached to (potentially counterfeit) packaging.

The international manufacturers' solution: of encoding the 'fingerprint' of the packaging into the unique identifier, stored in a database and printed directly on the packaging (making any paper markers obsolete), has not even been considered. The study therefore failed to provide a market overview, despite the fact that this solution was submitted to the study and is the only robust evidence that the pack is genuine.

Counterfeit products account for 0.6% of EU consumption, and counterfeiters regularly fake the paper stamps of low-price non-EU markets. Furthermore, in Ireland counterfeiting of tax stamps on tobacco products was a significant issue between 2009 & 2011 when the level of smuggling and illegally traded tobacco products was at its highest. There is nothing however, stopping counterfeiters from copying the tax stamp again. Therefore, the requirement for EU products should be proportionate and effective.

Option 4 (including the unique identifier for T&T on a removable paper stamp) is the least suitable solution for cigarette manufacturing, as there is neither suitable nor sufficient space for the paper marker on the pack. The unique identifiers of all packs in a carton have to be read to create the aggregation information, and the only location is the top and bottom surface of the pack. However, this surface is not big enough to accommodate a paper stamp. Additionally, a pre-printed unique identifier would not be compliant with the EUTPD nor the AITP, as both require specific manufacturing information as part of the identifier.

### Attachment C.1.1

### Calculations of cost/benefits

The calculations found in the study are based on inaccurate data, undisclosed assumptions and inappropriate methodology. This has led to meaningless results, exaggerated benefits, underestimated costs and provides a purely speculative assessment of the impact on manufacturers, trade and the Member States.

Additionally, the costs for manufacturers and economic operators do not include the adaptation of MRP, accounting, invoicing and warehousing systems in order to provide information such as customer, order and invoice numbers and payment records, for which the consultants do not present any compliant solution. This required information cannot be obtained from scanning and has to be obtained from significantly diverse systems and individual IT infrastructure.