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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 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
 - o f) Other

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

Text of 1 to 800 characters will be accepted

Intergraf a.i.s.b.l. is a European non- for profit association located in Brussels, Belgium representing the printing industry with a specialization in security printing (member associations in 20 countries). We provide a platform for security printers, suppliers and customers. Intergraf has developed standards for security printers and their suppliers for more than 15 years and initialized the development of the CWA 14641, CWA 15374 and latest the ISO 14298 standard "Management of Security Printing Processes". Intergraf has certified over 90 companies in more than 40 countries. Out of 28 countries of the EU 21 have tax stamps. These tax stamps are produced by European security printers. Out of these 21 security printers 16 are Intergraf ISO or CWA certified.

*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

Intergraf a.i.s.b.l. Avenue Louise 130A 1050 Brussels Belgium

- *A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):
 - Yes
 No
- *A.3.1. Please enter your registration number in the Transparency Register

15519132837-45

- *A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.
 - a297d8f8-dfef-4ad3-bb2d-ef6230c65a09/2009 Statutes.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	0	0
*System integrity (e.g. low risk of manipulation)	0	©	0	0	•	0
*Potential of reducing illicit trade	0	•	•	©	©	0
* Administrative/financial burden for economic operators	©	©	0	©	©	•
* Administrative/financial burden for public authorities	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	Appropriate Somewhat appropriate		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
*Potential of reducing illicit trade	0	•	•	0	0	0
* Administrative/financial burden for economic operators	0	©	0	©	•	•
* Administrative/financial burden for public authorities	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	0
*Ease of operation for users	•	©	0	•	•	•
*System integrity (e.g. low risk of manipulation)	0	•	•	•	•	•
*Potential of reducing illicit trade	0	•	0	0	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	•	•	•	•	•
* 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)
 - 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	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	•	•	•

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
*Interoperability	©	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	•

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	•
*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	•	•	•
* Administrative/financial burden for public authorities	©	•	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	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	0
* Administrative/financial burden for economic operators	0	•	0	•	0	•
* Administrative/financial burden for public authorities	0	•	0	©	•	•

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

C. Cost-benefit analysis

C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	©	©	•	•	•	•
*The cost analysis presented in section 11.3.2 of the Feasibility Study	©	©	©	©	©	•

D. Additional questions

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

*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)? 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.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)
 - e3128666-23aa-4e88-bc6b-9643e75f03ef/D7.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	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	•	•	•	0
*Scanning products upon dispatch from manufacturer's/importer's warehouse	0	•	•	•	0
*Scanning products upon receipt at distributor's/wholesaler's premises	•	•	•	•	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

Depending on the level of supervision our answers for the last 4 questions alternate between "third party auditor" or ""authorities". We do not have a clear preference for either of the two for scanning products on receipt or dispatch at manufacturer or distributor, or for aggregation of products.

aggregation of products.	
*D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which 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	of
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) • 5088f6cd-5c8c-4fe3-b201-bc498e1ebccb/D11.docx	
*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 in question D.12. above (max. 2 pages) • eb9a68d3-1c0a-46a6-abee-308fe80a396c/D13.docx	d to
*D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)? ② a) Provider of solutions to collect the data from the manufacturing and distribution chair ③ b) Provider of data storage services; ⑤ c) Another entity ⑥ 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)
 - 31535469-6eec-4180-8d5a-24b2432f07ed/D15.docx
- *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

It is obvious that illicit activity will try to bypass the traceability system. Only the customers as last part of the chain cannot be bypassed. We believe that our efforts to fight illicit trade will be far more effective when customers are also engaged to fight against illicit trade. In order to achieve this we need to raise the end customers' awareness and equip them with tools to check the authenticity of the products. That is why Member States' governments should undertake campaigns to raise awareness among citizen.

- D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)
 - f8d8ba71-0d24-494a-ab03-db48dc8360ad/D17 Intergraf Additional Information.docx

Contact

SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu









Attachment D.7

D7. Placement of serialized unique Identifier

It is recommended that the data (regarding TPD article 15) from the production line is stored in the traceability system and not in the code itself, especially when the unique identifier is applied on the package/item filled with product that will be stored and processed on finishing lines in the future. It is important that the unique identifier is applied before the final celophane packaging so that it serves as a protection of the identifier.

Attachment D.11

D.11. Please upload any additional comments relating to the method of putting the security feature n the pack referred to in question D.10 above (max. 2 pages)

If a fiscal stamp system is in place, it is important to use this existing fiscal stamp system and adapt it to the TPD articles in order to reduce costs and burden for authorities and economic operators.

D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)

One independent data storage should be placed in each Member State territory to provide authorities with tools (e.g. reports, alerts) to help fight illicit trade. Member State authorities need to have influence on the creation of tools that best fit their needs.

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)

The provider of the solution should develop the reporting and query tools together with the Member State authorities. Requirements for the reporting system might evolve over time and thus reports received from the traceability system should be revised periodically to ensure their relevance and successfully fight against illicit activity.

Attachment D.17

Intergraf a.i.s.b.l. is a European non- for profit association located in Brussels, Belgium representing the printing industry with a specialization in security printing with currently member associations in 20 European countries.

Intergraf's mission is to provide a platform for interaction of security printers, suppliers and customers. Intergraf promotes and protects their interests via certifications (for Security Printers, Hologram Manufacturers and Suppliers to Security Printers).

Intergraf has developed standards for security printers and their suppliers for more than 15 years and initialized the development of the CWA 14641, CWA 15374 and latest the ISO 14298 standard in cooperation with representatives from standardization institutes and industry experts from 25 countries and 5 continents.

The following standards were developed under the initiative of Intergraf:

CWA 14641 - Security Management System for Security Printing

CWA 15374 - Security Management System for suppliers to secure printing industry

ISO 14298 - Management of Security Printing Processes

All above mentioned standards are not product standards but process-oriented standards that evaluate the management of the processes within an organization.

Intergraf certifications started in 2000 and have ever since been a recognized reference for government and industry to guarantee a high quality security management system and to help the fight against counterfeiting of printed goods, such as ID documents, passports, credit cards, banknotes, stamps, tax stamps, tobacco and alcohol banderols, and other products produced by security printers.

The ISO standard for security printers, ISO 14298, specifies requirements for the management of security printing processes and guarantees maximum security from development to deployment of a printed product and is a transposition of the former CWA 14641. Besides the official and publicly available standard document, Intergraf provides confidential Implementation Guidelines and Intergraf Certification Requirements (ICR), exclusively developed for the security printing industry and the specific needs of this market.

Those requirements are confidential and are not publicly available due to the nature of the products and the highly secure industry.

Throughout the world, Intergraf certificates stand for trusted security printers and trusted suppliers to the security printing industry and are therefore integrated in many tenders every year – over 90 companies with more than 95 certified management systems in more than 40 countries choose to rely on us.

Well-known associations such as the UPU (Universal Postal Union, a United Nations organisation) and IHMA (International Hologram Manufacturers Association) recognize and recommend certification according to ISO 14298:2013 and the Intergraf Certification Requirements (ICR). The above mentioned certifications are used by ministries and governments as a requirement for organizations to participate in their tenders.

This is reflected in Annex 4 of the "Analysis and Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features". This annex lists the 28 countries of the EU out of which 21 have tax stamps. These tax stamps are produced by European security printers. Out of these 21 security printers 16 are Intergraf ISO or CWA certified.