Case Id: f4637f1b-e884-4f45-8817-7db0ea556cb7

Date: 31/07/2015 11:01:33

# 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 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.c. Please specify:
  - i) Provider of solutions for tracking and tracing systems (or parts thereof)
  - ii) Provider of solutions for security features (or parts thereof)
  - iii) Data Management Providers (or parts thereof)

\*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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FATA Logistic Systems - Strada Statale 24 km. 12 - 10044 Pianezza (Torino) Italy - amm.del@fatalogistic.it - +390119668473 - +39335291709.

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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.3.1. Please enter your registration number in the Transparency Register

Mother company Finmeccanica SpA is registered in the Transparency Register of the European Commission with number 02550382403-01

- \*A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.
  - 94f7a3fc-5394-41b1-b17e-d7aae5cc2378/FATA Logistic Systems Extract from trade registry V.1.0.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	0	0
* Administrative/financial burden for economic operators	•	•	0	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	0	0
*System integrity (e.g. low risk of manipulation)	0	©	0	•	•	0
*Potential of reducing illicit trade	0	•	0	0	0	0
* Administrative/financial burden for economic operators	0	©	0	•	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	•	0	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.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	•	•	•	•	•
* 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)
  - c25ba70b-3a42-408f-9de2-897890add69a/FATA Logistic Systems B.1.5.upload.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
*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	0	•	•
* Administrative/financial burden for public authorities	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	0	•	0
*Ease of operation for users	0	©	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	•	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	0
*Ease of operation for users	•	•	0	•	•	0
*System integrity (e.g. low risk of manipulation)	•	•	0	•	•	•
*Potential of reducing illicit trade	•	©	©	©	•	0
* Administrative/financial burden for economic operators	0	©	0	•	•	0
* Administrative/financial burden for public authorities	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
*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
*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)
  - cc228b4d-554c-4acc-9cae-d4c6c744ca69/FATA Logistic Systems B.2.5.upload.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)
  - f0bb01e5-e3a5-4dad-b075-c94dbb9b0d7e/FATA Logistic Systems C.1.1.upload.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.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 or similar.

## \*D.1.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

A code which allows to include the information requested by the Directive 2014/40 for product authentication and could be both eyes and machine readable.

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
Best solution in our opinion is: one data carrier selected for each step of the supply chain and data made available (reversed) in a unique repository controlled and run by the "data storage provider" selected and contracted by the tobacco manufacturers and certified by MS Authorities, as requested by the Directive; most likely the first data carrier and data base should be provided by any single tobacco manufacturer and next ones by the distributor/s in each MS, etc.
*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
<ul> <li>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)</li> <li>6892a5dc-7b8a-4819-8cc6-3b813dcce627/FATA Logistic Systems - D.5.upload.pdf</li> </ul>
*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	•	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

In the supervision of the activities listed above, suggest to replace "third party auditor" by "data storage provider" as described in Directive 2014/40.

- 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 b) A security 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

As we indicated above, preferred solution for security feature is: tear tape with taggant ink (covert element) and script (overt element) defined by MS Authorities. The taggant ink should be certified by the "data storage provider" who should also be responsible of distributing and updating right scanners to MS Authorities and Controlling Institutions.

Unique identifier should be "protected" through fingerprint technology.

- 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)
- $^{\star}$ 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)
  - 846000f7-478a-42e2-8e5d-01a32928a538/FATA Logistic Systems D.13.upload.pdf
- \*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)
  - · a8fb92af-d135-469e-8f23-ac8af3672213/FATA Logistic Systems D.15.upload.pdf
- \*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
  - O c) No opinion
- D.16.a. If yes, please explain your considerations

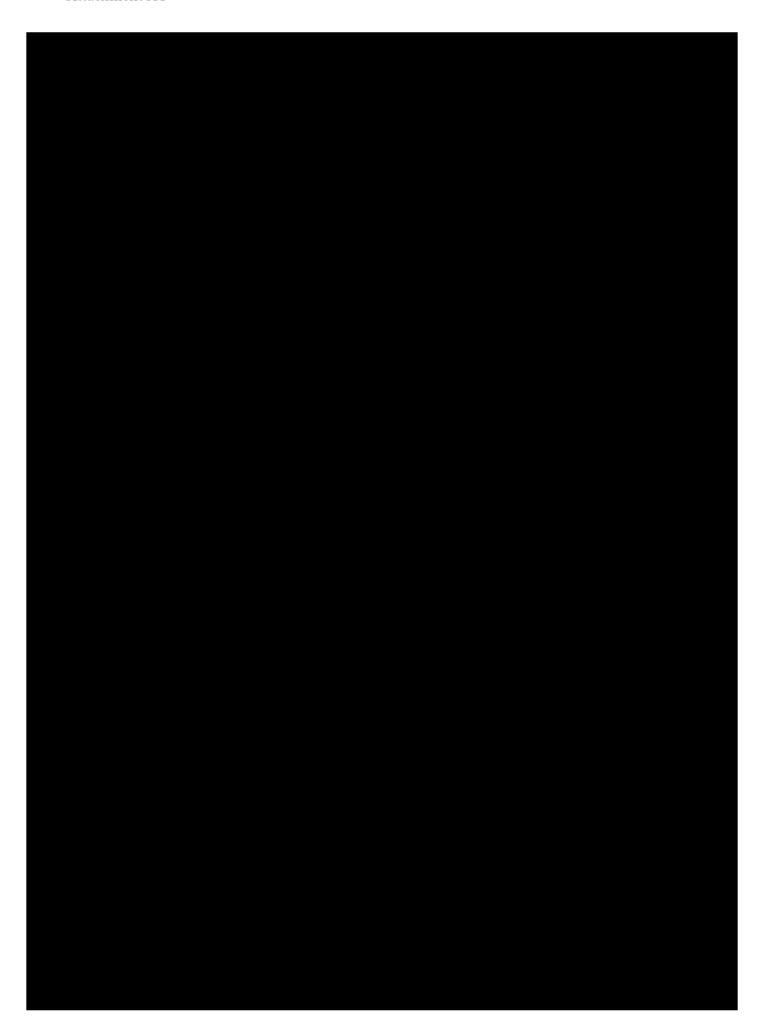
Text of 1 to 800 characters will be accepted

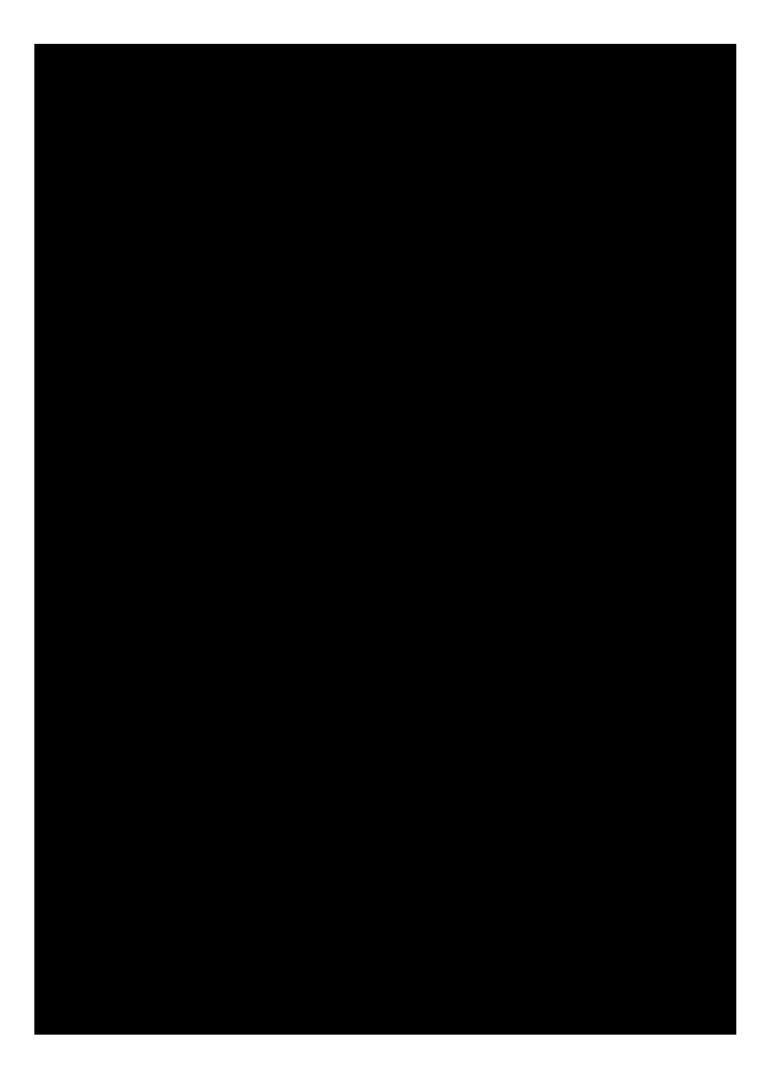
Integrity will be affected by the consumers being able to decode and control the unique identifier. Spreading the control of the code and allowing the consumer to access the information, we may expect that the effectiveness of the system will be improved at great extent. To fight illicit trade require controlling as much as possible the unique identifier.

D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)

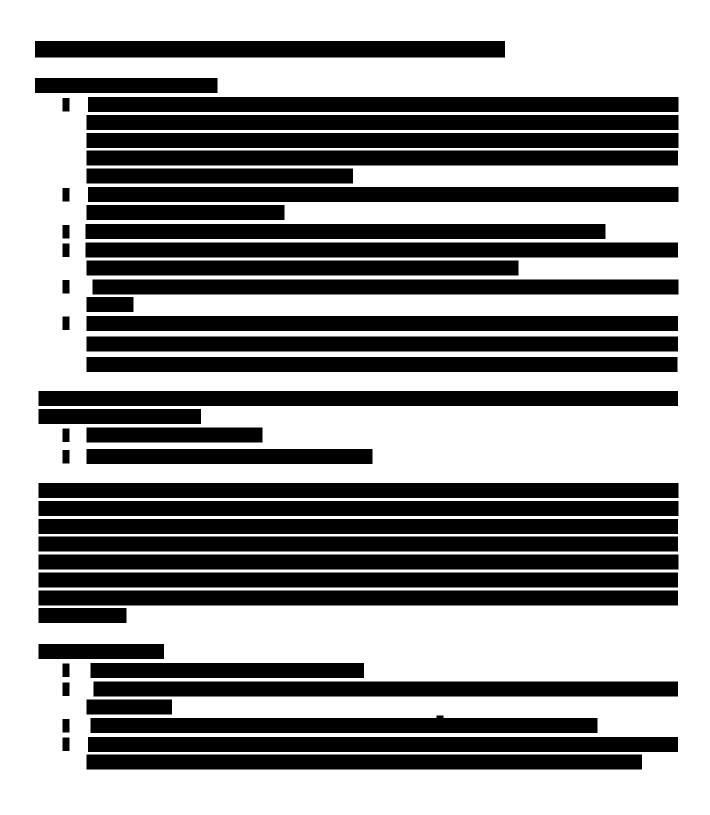
## Contact

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





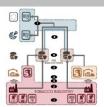




## **CONTENT SUMMARY**

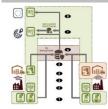
## **OPTION 1**

## **COMMENTS**



- Standards set by the Commission but tobaccomanufacturers responsible for the operation of T&T system.
- Data repositories separate for each tobacco manufacturer.
- Solution endorsed by authorities across the EU, including OLAF.
- Proven effective over 10 years of operation under the EC Agreement.
- Based on the industry standards, operated by companies having more than 90% market share in the EU.
- Low administrative burden for EU & MS.
- Allow to better focus on supply chain processes.

## **OPTION 2**



- Single T&T system across the EU
- Operated by one or more independent solution providers
- Single EU data repository

- No independence requirement contained in 2014/40.
- Integrity of data at risk.
- Replicating data repositories to MS increases costs tremendously.
- No flexibility of solution providers in MS.
- Increased cost and operational burden for manufacturers and operators.

Complex manufacturing environment, potentially several solutions

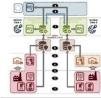
installed on a single production line, each solution operated by a

different solution provider; almost impossible to implement.

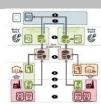
- Potential manufacturing process down-time.
- Reduced flexibility for tobacco manufacturers.
- Proprietary equipment needed to retrieve T&T data.

Unnecessarily increases costs of data storage.

## **OPTION 3**



- Standards set by the Commission.
- Operated by either tobacco manufacturers (3A) or solution providers (3B), depending on MS decision.
- Data repositories separate for each MS
  - Option 3B: 28 data repositories and potentially 28 solution providers



- Standards set by the Commission, merging T&T and security feature.
- Requires a label with a pre-printed unique code to be glued to a pack (tax stamp or other label)
- Data repositories separate for each MS
- Potentially 28 solution providers
- Cost estimates inaccurate (confront with actual cost of paper stamps to realize)
- Data aggregation potentially not feasible

- MS authorities appoint Data Management providers: contrary to
- 2014/40 Directive.

## **OPTION 4**

- Does not meet TPD requirements as some data will not be included in the unique identifier, e.g., date and time of production.
- In case of products for export, 2 labels could be required to be applied.
- Unnecessarily increases costs of data storage.
- Complex manufacturing environment with potentially several solutions installed on a single production line.
- Not feasible on all production lines.
- "Aggregation" almost impossible to implement.
- No control on SF stocks as it is today with paper stamps.

## B.2.5 - EU FEASIBILITY REPORT - COMMENTS ON SECURITY FEATURE

## **SECURITY FEATURE (TPD Art. 16.)**

Main comment to the indication of the Report on this article:

- We believe that the purpose established by Directive 2014/40 for the "security feature" is mainly an "anti-tampering" secure element to prove that the product has not been manipulated (at least this is the strict interpretation of the translation of Art. 15 into Italian language);
- The "authentication" of the product being completely provided through the information included in the unique identifier;
- So, the anti-tampering secure element should be a cheap and simple one with overt and covert information as required by Art. 15 of the Directive;
- At the same time the unique identifier should be protected from the only possible fraud: "cloning";
- There are several technologies, more or less expensive, which can do that (fingerprint of the products packs, fingerprint of the printers who are authorized to print the unique identifier on the product lines (as bullets shut by a gun), etc.);
- These technologies should have been analyzed in the Report.

So, we are very much in favor of and suggest to adopting:

- Simple and cheap security features as an anti-tampering proof (one potential technology could be a tear tape with taggant ink as covert element and MS symbols and scripts as overt element);
- Use fingerprint technologies to protect the unique identifier from cloning and prove authenticity of the packs.

## Attachment C.1.1

## C.1.1 - EU FEASIBILITY REPORT - COST BENEFITS ANALYSIS

## **BENEFITS**

- We believe that the impact of T&T and SF on illicit trade could be higher;
- We made an estimation for Italy:
  - Agree on 30% reduction on contraband;
  - Counterfeiting could be reduced by 90 % excluding the phenomenon of "cheap whites"

## **COSTS**

- When considering Option 1 of T&T, investments already done by tobacco manufacturers in this direction should be considered and not included in the analysis; excluding those investments the cost of Option 1 should be reduced of a factor 10 roughly;
- On the contrary, costs of Option 4 are underestimated in our opinion of a factor 3, according to the actual cost of paper stamp in Italy especially according proposal to include new features similar to the one requested by Directive 2014/40 in this case;
- Even costs of implementation and running of the IT solution of Option 1 for MS Authorities are over estimated: in case the IT solution built by DCTA would be adopted by tobacco manufacturers, royalty-free licenses are available for all tobacco manufacturers and MS Authorities. So the implementation and running costs are lower than the ones in the Report.

## Attachment D.5

# D.5. – Option for Data Carrier

- Human readable code is the easiest one to read for consumers; in the future consumers should be involved in controlling the authenticity of the products they smoke and in the laws they have to respect.
- Machine readable code is the way of including more information in the coding through covert element.

## Attachment D.13

## D.13 – Independent data storage

- Once the t&t process has been defined by implementation regulation, different storages interoperable among different operators in the supply chain, should be used;
- The data should be carried by different operators working in the supply chain: the tobacco manufacturers should provide initial repository and carry data until the products are their property;
- At certain steps data should be reversed (duplicated) into a single efficient data base managed by the data storing company for each MS.
- The independent data storing company will be responsible of data included in the official repository;
- Authorities can access that repository any time through special IT tool to control all the relevant information for product authentication and t & t.

## Attachment D.15

# D.15. Development of reporting

Both are well placed for this operation. It is very likely that in most cases they coincide. The provider of data storage will be the official certified interface to MS Authorities and is a trustable entity independent from tobacco manufacturers