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.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

Advanced Track and Trace
99 Avenue de la Chataigneraie
92504 Rueil Malmaison Cedex
France

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.

- a9eb4042-ba75-459a-bac9-e60892638f52/Kbis 050615 eng.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)

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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)

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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)

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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)

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B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
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B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below
B.2.1. Option 1: a security feature using authentication technologies similar to a modern tax stamp
(for further details on this option, please consult section 9.2 of the Feasibility Study)

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### 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)

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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)

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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)

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B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)
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C. Cost-benefit analysis
C.1. Do you agree with?

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D. Additional questions

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

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

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

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

Text of 1 to 400 characters will be accepted


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.a. Please indicate your preferred data carrier and explain why

Text of 1 to 400 characters will be accepted

Datamatrix on a stamp is an interesting option: readability, content, common use in supply chain...

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?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Economic operator involved in the tobacco trade without specific supervision</th>
<th>Economic operator involved in the tobacco trade supervised by the third party auditor</th>
<th>Economic operator involved in the tobacco trade supervised by the authorities</th>
<th>Independent third party</th>
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<td>Generating serialized unique identifiers</td>
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<td>Scanning products upon dispatch from manufacturer's/importer's warehouse</td>
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D.9. In relation to question D.8. above, please specify any other measures that your organisation considers relevant

A declaration obligation by the stakeholders that allows the update of the authorities or third party's database to reflect the goods shipping and arrival. Database updates or lack of would underline issues involving potential further checks.

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/pouch/item through a different method;
- 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
  b) No
  c) No opinion

D.16.a. If yes, please explain your considerations

Text of 1 to 800 characters will be accepted

It might be negatively perceived that the consumer is excluded from the solution. It may be easy to give a certain level of information to the consumer.

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 B.1.5

1 - Advanced Track & Trace introduction

« Advanced Track & Trace® provides public & private institutions with advanced technologies to protect documents, banknotes and products – strong physical authentication, unit identification and traceability solutions, protection of data integrity and large capacity secured data containers.

Internationally rolled-out, Advanced Track & Trace® innovative solutions offer the highest level of security, to detect frauds on any document such as ID cards, badges, licenses, passports, visas, tax stamps, legal or private documents (labels, secure packaging, invoices, tickets...).

Advanced Track & Trace® works along with major international banking establishments, and embeds its solutions into banknotes and other secure applications. As an international security expert company, Advanced Track & Trace® collaborates with customs authorities, institutions and international groups in all regions and all activity sectors sensitive to illicit trade: alcohol, tobacco, wines and spirits, pharmaceuticals, cosmetics, electronics, spare parts, food, luxury...

Each month, controls of items secured by Advanced Track & Trace® generate tenth of thousands of readings in the field all around the globe. ATT technologies have been applied on more than 50 billion units of products/documents/banknotes since 10 years among which around 10 billions of tax Stamps.

2 - Comments on Track and Trace Options from the report of Eurogroup Consulting

Option 1 Tobacco industry solutions for track and trace

- As the issues of track and trace for tobacco were raised at least partially from some of the producers first, and, as any constraint and tighter control cannot come without drawbacks for the industry, second, States cannot fully delegate this responsibility to those whose products are creating the issue.
- Nevertheless as the industry is willing to cooperate and runs as a matter of fact the production and initial tracking step, shouldn’t it be involved? The FCTC protocol implies that information should at least partially come from the point of production.

Option 2 direct marking solutions

- This solution might be expensive for the Government and/or the Tobacco manufacturers due to its hardware and systems necessary to setup at each production site and due to management fully outsourced from the tobacco industry
- Setup might be delayed due to the intricacies, the operational impact in each unit producing tobacco where an outside operator and material should be setup and working.
- The solution apart from being very long to setup might be practically difficult to remove and to be switched off to another supply if needed due to the nature of the system. This might create static situations with a negative impact on changes and costs.
- The solution may not deal with the goods imported into the EEC as the system would not be decided on a worldwide basis. The fraud might go along that route to import goods within the EEC without being tracked and traced.
Option 3 mix of both 1 and 2 – Tobacco industry system and direct marking

- This solution does not bring anything better than any of the first 2 options except adding an interoperability matter as stated in the report. This brings the number of proposal based on direct marking to a total of 3 over 4 scenarios.

Option 4 linking unique ID and traceability

- This scenario seems to be the most interesting and there are various options that could be studied and might be split into several.
  - The report underlines disadvantages regarding application that have been often overcome since a long time that excise stamps are operational.
- Whether the application-on-line has to be operated by an independent provider as suggested in the report is to be developed and analyzed with pros and cons.
  - This would thicken the layer of supply and the value of the business for the providers, undoubtedly. Hardware, software, operations, maintenance, cooperation with the manufacturer in every site, etc...
  - This will not make implementation easier within the tobacco manufacturer premises as the solution would not be under their operating control.
  - The cost implications can be extremely significant as a supplementary layer of costs is added while today this is born by the industry:
    - It might be considered to stay under the responsibility of the tobacco manufacturer to apply the stamps as of today and on top of it to read them on line. What are the drawbacks?
- It could be considered to keep the responsibility to the tobacco manufacturer:
  - Every product is marked with government supplied unique secured IDs. This can be controlled physically as well by periodic audits regarding methods and reliability plus reports of deliveries against supplies for the traceability of those unique IDs.
  - Reading equipment is setup under their responsibility to read the codes when implemented. They would have to get it working.
  - Traceability information are reported to government/solution provider database with reliable correspondence that can be ensured through periodic audit
  - Aggregation is managed properly by tobacco producer before shipping to allocate unique IDs with correct supply chain encoding on packaging.

- When option 4 is based on excise stamps, it could bring benefits
  - Stamps can be modernized in terms of security features and have already been in certain countries: they can be counterfeit resistant
  - Stamps can be produced and distributed under tight state control with unique registered IDs, tobacco site and product related.
Stamps are affixed already today by the tobacco manufacturer worldwide so there is little cost involved and a quick setup is possible.

Stamps can solve the imported good issue as those stamps can be mandatory for all imports within the EEC and tobacco manufacturer abroad are generally equipped to affix them as excise stamps exist worldwide.

Most of all, an interoperable solution based on public standard can be setup while preserving competition on security feature / stamp supply.

The stamps can have a minimum features in common:

- The EEC is used to setup this kind of standard where each state remains in charge of defining his document while a recommendation on the minimum level of security is prescribed without damaging the competitive landscape.
  - See the recommendations for the European passport as a good example.

The interoperability should be focused first on the reading of the serialized code by:

- Using commonly in the EEC a world well-known and acknowledged supply chain international standard: the Datamatrix.
- This code is recommended already by the EEC authorities for the pharmaceutical industry for this very same reason.
- It is the code proposed on outside packaging by the tobacco producers themselves for the aggregation process (pack to carton and so on) and for all the supply chain along the des-aggregation process.
- For the same reason that it is the good code for the supply chain, it is the good code for the tobacco manufacturer.
- They might not complain they have to read it: it is a standard, they propose it themselves for their customers, it is the quickest standard to read and it is fully interoperable.
- The Datamatrix can contain a certain amount of information and can be designed to have European interoperability.
- As stated in the report no code on the box could contain all the information required by FCTC protocol.
- Therefore it could be the duty of the tobacco manufacturer to read this code at proper time during production and then, to send the corresponding traceability data in accordance with the FCTC protocol and the TPD directive to the government controlled or service provider database.
- Tracing stamps numbers that remain without any data allocated by the manufacturer can be easily traced through the update of the government controlled or service provider database.
- Regular audit can check that the system allocates information correctly.

Stamps can help EEC to take the lead to help tracking and tracing for exported products outside of the EEC and therefore helping other countries to fight against illicit trade.

As long as a FCTC compliant system has not been put in place in country of destination of goods produced in Europe, but that still falls under the FCTC protocol, a specific export stamp can be applied on the tobacco pack using the same principle and technologies.
- The stamp can be distinguished by a shape, a colour or something else to identify it as a “to be exported outside of EEC good”.
- The physical location has to be specified as it should be different from the usual excise stamp place location on the pack in case a non-interoperable classical excise stamp is already required by the country of destination.
- In this situation the constraint for the tobacco industry would be to apply 2 stamps: one for the export traceability in Europe and one for the excise stamp of the country of destination.
- This is a constraint but this is what requires the FCTC protocol: to trace all goods in the country of production and to give the information on an international basis.

Conclusion:

The majority of the the scenarios encompassed are focusing on direct marking whether tobacco industry based or independent provider based where in both cases one solution only has been marketed so far.

The traceability through unique IDs applied on stamps, meaning an upgrade of many existing excise stamps may be a good solution. They would not bring along the serious concerns in terms of cost, speed of implementation and competition landscape of option 2.

Datamatrix as the standard supply chain code widely used and already considered by tobacco supplier for the their aggregated packaging could as well be applied effectively on the stamp allowing interoperability, cost efficiency, easier implementation and preserved competition between suppliers.

The tobacco industry should be involved as they are anyway suppliers of the data for the FCTC protocol and operators of the production chains of the industry. They would be in charge, on top of application of the stamps, as of today, of reading the stamps IDs and sending the relevant traceability data while making sure these IDs will be related as well with the aggregated data from the cartons and pallets necessary for the supply chain next traceability steps. The authorities rules, the stakeholders apply, operate and are checked.

There might be no need to outsource and to bear the extra cost from the independent providers that would supply and operate this solution within the tobacco premises. The authorities would supply to the operators the interoperable secured unique IDs and maintain a database with those IDs and the corresponding information received from the all the tobacco operators along international and European tobacco traceability regulations.

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Attachment B.2.5

Security features options 1 to 4

1 – Option 1 – Similar to Tax Stamp with security features

- We understand this scenario as to be potentially “tax stamp based” and not only “similar tax stamp based”
- Drawbacks underlined in the report regarding stamp on line laying have, we think, long been overcome by the industry as excise stamps exist since a long time and are affixed on line already.
- Security feature can be chosen by each country as in the European Passport where only a minimum requirement is imposed by Europe authorities. Then communications is made between countries to control each other solutions in an interoperable way.
  - The way the industry has been structured to ensure interoperability is an interesting reference as focus has been put on communications protocol, information storage together with minimum generic requirements rather than described detailed solution and security feature selection.

2 - Option 2 – security feature aside from a direct marked unique ID on the tobacco pack, direct marking to be with semi covert feature to be secured as well

- We are not grasping the purpose of having together but aside from each other stamps and direct marking? Why separate the digital marking from the stamp as digital marking can be on the stamp as well?
- It is underlined that the stamp is no longer secured with a semi covert feature because it was moved to direct marking. Why then pushing direct marking aside from the stamp?
- If the stamp carries in a valid manner the security features why not add the digital unique ID on it instead of splitting?

3 – Option 3 – Addition of material fingerprinting

- The example given relies more on paper fingerprinting it seems. It is quickly reviewed and considered to be worth evaluated further as an interesting concept.
- While this one implies equipment to read the substrates, there are other techniques that might be lighter and already proven in terms of implementations.
- Those technologies rely on linking physical and digital information to increase the security level.
As an example physical an digital can be linked as following (example based on ATT technology marketed since 2005)

- The background of the item is printed using various technique (offset,...) with a chosen substrate, ink and machine defining a context that will have certain peculiarities that can be recorded as the "printing context" fingerprinting.
- This can be linked to the digital variable data (unique IDs) included into the code that is printed later on, on the item, or printed simultaneously if numeric printing: a link counterfeit resistant is created.
- The check is done using a smartphone that will read both the variable code and the "context fingerprint" to check this is the genuine one with the consistent and related variable data.
- No specific hardware is required at tobacco manufacturer level, very little at printing stage and smartphone or scans are around anywhere for the reading.

4 – Option 4 – Including a machine readable code

- This option might be important to develop solutions for authentication on the field to allow inspectors to be efficient by being able to assert genuine or false labels, on the spot, while not waiting for remote expert answers.
- Solution exists to read variable data and to check authenticity through such more and more common tools as smartphones with or without add-ons.
- “Authentication in the field capabilities” of the solution is a critical evaluation factor to fight against illicit trade.
- The legal value of the solution has to be asserted as well to be confident once the fake detected the justice will accept the security as a legally valid proof.

5 – Code content

- It is rightly stated that the code cannot anyway contain all the information required by the FCTC protocol or the European directive TPD.
- Therefore the focus must be on having interoperable IDs for database queries giving full access to information when deemed necessary.
- This why we think Datamatrix can be a good option.
- Europe authorities made this choice already for the pharmaceutical industry.
- The solution recommended is based on proposing a common on-line production recording system based on standard interoperable code where states can still choose their solution providers and private stakeholders to select and install the required hardware.

6 – Supply chain issues
The report gives details on the IT side of things and on supply chain management: this is a classical supply chain issue with not in general the same providers as secured track and trace: those are pure IT services companies with competencies in traditional supply chain IT. This know-how can be linked with the central national database management which is mainly an IT issue as well.

As far as the code is defined at the industry level and is a standard for the world of logistics, and, regulations are issued on what must be traced by who, the implementations could be left to the stakeholders. The tobacco producer having setup under the new rule the stamp IDs correlation with the aggregation Datamatrix codes on the packaging of the individual packs, the track and trace can be followed up to the last selling point by standard supply chain practices.

It is to be further studied for efficiency and cost reasons whether several steps of implementations cannot be considered by each country and whether here again the private stakeholder can be in charge of complying with the requirement to update the national database along the new rules. They will be able to do so once the tobacco production sites have provided the aggregation/des-aggregation codes with links to the government issued unique IDs from the stamps.

Conclusion:

We recommend a scenario where digital and physical are, first, linked to automate the check on the spot of authenticity with, second, immediate access to variable information of the item controlled, both principles backed by a secured database connection as is already practised in other industries since some years...

We suggest an implementation in several steps with subsidiarity principle towards the private stakeholders: when they can do it thanks to the use of standard public solutions, they are in charge to implement the regulations while solution providers delegated by authorities do not meddle into the practical operations neither at the tobacco packaging site nor all along the supply chain locations. They receive in due time and due format the updates and information from the responsive stakeholders, tobacco manufacturer and supply chain actors. The authorities –or by delegation certification companies- can launch checks whenever estimated necessary.