Public 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.

Introduction

This is a public consultation on the implementation of an EU system for traceability and security features for tobacco products, as required under Articles 15 and 16 of the Tobacco Products Directive 2014/40 /EU (TPD). The purpose of this consultation is to seek comments from the general public and interested parties, such as consumers, retailers of finished tobacco products, manufacturers of finished tobacco products, wholesalers and distributers of finished tobacco products, providers of solutions for operating traceability, security feature or data storage systems, and governmental and non-governmental organisations active in the area of tobacco control and the fight against illicit trade.

The basis for the consultation is the Commission's Inception Impact Assessment. This document develops the main policy options currently under consideration for implementing the system for traceability and security features provided for under Articles 15 and 16 TPD. These policy options are outlined in Table 4 of the Inception Impact Assessment (page 8).

As the objective of this public consultation is, among others, to gain confirmation or otherwise of the assumptions made regarding the policy options mentioned above, **those participating are strongly advised to review the Inception Impact Assessment before responding**. The comments received in the course of this consultation will provide input for the ongoing implementation work on the future EU system.

Stakeholders are invited to submit their responses to this consultation via the survey form below until **4 November 2016**.

The survey form 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. Submissions

should - where possible - be in English.

In the case of corporate groups, one single reply should be prepared. For responses from governmental organisations not representing a national position, the reply should explain 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 see here for information on rules governing personal data protection and consult the privacy statement provided on the consultation webpage). In the case of submissions by corporate groups, respondents are asked not to upload personal data of individuals.

Please note that organisations falling under the following respondent groups should register in the Transparency Register before they begin to answer the questions:

- Manufacturers of tobacco products destined for consumers (finished tobacco products)
- Operators involved in the supply chain of finished tobacco products (excluding retail)
- Providers of solutions for operating traceability, security features or data storage
- Non-Governmental Organisations

The submissions of non-registered organisations will be published separately from those of registered ones and considered as the input of individuals.

The Commission reserves the right to contact you to request further explanation and/or justification of your calculations and/or the reasoning on which your responses rely. You may also be requested to provide further evidence for your detailed replies.

Answers that do not comply with the overall specifications outlined above cannot be considered.

A. Respondent details

* A1. Please identify which respondent group you fall under:

- ☐ a) Consumer/member of the general public
- ☐ b) Retailer of finished tobacco products
- ☐ c) Manufacturer of tobacco products destined for consumers (finished tobacco products)
- ☐ d) Operator involved in the supply chain of finished tobacco products (excluding retail)
- ☑ e) Provider of solutions for traceability, security features or data storage
- ☐ f) Governmental organisation
- ☐ g) NGO
- ☐ h) Other organisation

If you fall under groups **b)**, **c)**, **d)** or **e)** above, please indicate if you are a small or medium sized enterprise as defined in [Commission Recommendation 2003/361/EC](#) (i.e. an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.)

○ Yes
● No

If other, please specify

Text of 1 to 800 characters will be accepted

██

If other, please specify

Text of 1 to 800 characters will be accepted

A6. If you fall under respondent group **e)** above, please indicate your main area of activity (multiple reponse options possible):

☑ Provider of solutions for tracking and tracing systems (or parts thereof)
☑ Provider of solutions for security features (or parts thereof)
☐ Data Management Providers (or parts thereof)

B. Respondant contact details

B2. In the case of organisations, please provide the organisation's name, address, email, telephone number and, 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

B3. Please indicate if your organisation is registered in the [Transparency Register of the European Commission](#)* (unless you fall under respondent groups **a)**, **b)** or **f)** of Question 1A above):
(*Please note that organisations falling under the relevant respondent groups should register in the Transparency Register before they begin to answer the questions. The submissions of non-registered organisations will be published separately from those of registered ones and considered as the input of individuals.)

- ⦿ Yes
- ○ No

If you indicated yes, please enter your Transparency Register registration number:

Text of 1 to 20 characters will be accepted

Where applicable please upload extract from the trade or other relevant registry confirming the activity indicated under Question A1 (English translation where possible)

* B4. Please state your preference with regard to the publication of your contribution
(*Please note that regardless of the option chosen,your contribution may be subject to a request for access to documents under [Regulation 1049/2001](). In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.*
)

○ My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication

● My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication

○ I do not agree that my contribution will be published at all.

C. Consultation questions

Please carefully read the [Inception Impact Assessment]() document before answering the questionnaire

Questions on the governance model

* C1. Out of the three governance models outlined in the Inception Impact Assessment for the traceability system for tobacco products, which one do you consider most suitable for operating the traceability system from your perspective:

○ Option A1: industry operated solution
● Option A2: third party operated solution
○ Option A3: mixed solution (industry and third party)
○ No opinion

* C2. Do you agree that the industry operated model (option A1) will require, on the part of the public authorities, additional control measures to ensure traceability of tobacco products?

● Yes
○ No
○ No opinion

* C3. Do you consider that traceability of tobacco products can only be achieved on condition that the supply chain is controlled by a third party independent from the tobacco industry?

● Yes
○ No
○ No opinion

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* C4. If options A1 and A2 are to be compared in terms of their overall impact on cost per pack of product (excluding potential additional costs for the public authorities related to monitoring and enforcement in option A1), do you consider*

- ○ Option A1 to be cheaper than option A2
- ○ Both options to have the same cost impact
- ● Option A1 to be more expensive that option A2
- ○ No opinion

*Subquestion a) to question C4: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in establishing and operating the traceability system under option A1 (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)? *Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products*

Text of 1 to 1500 characters will be accepted

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The operation by the Industry will imperatively require both National and EU
supervisory bodies to guarantee independance, compliance with both national
and EU relevant legislation and interoperability between member states.
The consequence is a triple level management system with induced Financial
costs and risks of misfunctions

Cost impact estimated 1.5
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Subquestion b) to question C4: What is your estimate of the average likely increase in the cost of a pack of product incurred in establishing and operating the traceability system under option A2 (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?

Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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If traceability system is controlled by a 1/3 party operator, the last one
shall be either a government body or a Trusted Partner; as such he will be
fully responsible for the system compliance, operation  and guarantee of
interoperability with other member states. This national governance model
gives more flexibility, is more inclusive of existing solutions, and limit
the cost of operation.
Assuming that a single or restricted set of data carrier has be set in force
for the program, that a serialized security device has to be applied on each
TP and the operation made by a tiers body at national level or European
level, the label nature and shape may differ from a MS to another one, in
order to take in account, the existing security solutions that may not
change. The tiers party solution in country without any tax stamp program
will have a smaller imprint on production costs even if the industry will
have to invest in labelling machine (investment made also equally in option
B). Cost for the industry side will be the same: labelling machine and
aggregation marking devices on cartridges, boxes will in all the cases remain
costs borne by industry. In this option all the coordination work with
industry is managed with a third party which will require less resources than
option 1 and les costs.
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* C5. Do you agree that a mixed model of governance, in which the choice of governance is separately made with respect to each distinct technological block/process (e.g. generation, printing/affixing and visual control of a unique identifier) can both provide for full traceability of tobacco products and mitigate the overall public-private cost of establishing and operating the system?

- ⦿ Yes
- ○ No
- ○ No opinion

C6. Would you like to add any comments or suggestions on the choice of the governance model?

Text of 1 to 1500 characters will be accepted

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The mixed Governance model is the most efficient : 1. it preserves each
member state' sovereign functions on tax stamps systems, 2. give flexibility
for additional functionnalities per country, 3. takes into account existing
systems, and 4.still can guarantee EU relevant legislation compliance
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Questions on the data storage location

* C7. Out of the two data storage locations outlined in the Inception Impact Assessment, which option do you consider most suitable from your perspective:

- ○ Option B1: centralised data storage
- ● Option B2: decentralised data storage
- ○ No opinion

* C8. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that centralised data storage can provide for important economies of scale (construed as savings in costs gained by an increased level of centralisation), in particular given the related costs of interconnectivity and interoperability present in the option of decentralised data storage?*

- ○ Yes
- ● No
- ○ No opinion

Subquestion to question C8: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

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In terms of development costs: centralised data storage will require a strong
coordination between the components from the various providers to operate
between all the involved countries. This effort can be managed more easily
with decentralized solutions requiring only to make to work together
databases specific to each country.
In terms of exploitation costs: in the past overcharge costs where induced
when you fragmented a database between several host operators by the
replication of basic infrastructures and maintenance effort between those
providers. With cloud hosting, the overcharge is limited by private cloud
pooling of infrastructures and maintenance between the various host users.
Economies in the development phases and during probable evolution phases will
compensate this limited overcharge.
Sovereignty, integrity and confidentiality will be guarantee by trusted
partner
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* C9. Which type of data storage represents higher risks in terms of time required to access data and/or potential downtimes?*

- ◉ Centralised data storage
- ○ Decentralised data storage
- ○ No opinion

Subquestion to question C9: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

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Centralised data storage are more sensitive to major breakdown. It will be
easier for hackers to attack such a structure, to parasite their working
process, and to limit their capacity of answers. If centralized data storage
is deployed, it will be with a limited level of replication (probably 3), but
if 27 countries have their own database (smaller) and share them to cover the
content of other ones with last in date Peer-to-Peer technologies like (DISH
ref.), consequences of a down time or denial of access from a peer will be
reduced to a delay in accessing the data. So we strongly recommend
decentralized solution. The best example of robustness of such approach with
a very interesting economic model is the well-known service Spotify or the
Bitcoin money with its blockchain technology.
As an example, such decentralization system is provided by Estonian
administration backup system.
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* C10. In the case of a decentralised data storage, how should data be split among individual data storages:

- ◉ Geographic decentralisation with regional/national data storages
- ○ Product decentralisation with all the data on a single product stored in one place
- ○ Other option
- ○ No opinion

* C11. If the option of geographic decentralisation of data storages is considered, the relevant data on a given product should be placed

- ○ In the storage of the region/country of product origin
- ◉ In the storage of the region/country of intended retail market
- ○ In all the regional/national data storages of a given product's presence, incl. transit countries
- ○ No opinion

*Subquestion to question C11: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

> The stakeholder most motivated will be the tax beneficiary and consequently
> the relevant data on a given product should be placed in the region / country
> of intended retail market.

C12. Would you like to add any comments or suggestions on the choice of the data storage location?

Text of 1 to 1500 characters will be accepted

> Strategic consideration drives us to give tools to the most involved
> stakeholder, which is the country of the retail market.
> Sovereignty (fiscal secrecy, data privacy of tax collection) issues is key
> decision factor in the choice of location of the data storage

Questions on the allowed data carriers

* C13. Out of the three options for data carriers outlined in the Inception Impact Assessment which one do you consider most suitable for operating the traceability system from your perspective

- ◉ Option C1: system with a single data carrier
- ○ Option C2: system with a limited variety of data carriers
- ○ Option C3: free system allowing any exisiting data carrier
- ○ No opinion

* C14. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that a system with a single data carrier may offer insufficient flexibility in view of different requirements of various economic operators, including small and medium enterprises?

- ○ Yes
- ◉ No
- ○ No opinion

* C15. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that a free system (allowing any existing data carrier) introduces a risk that certain data carriers will not be readable by all the scanners installed in the system and that its functioning would require frequent updates of the scanners, which may not be technically feasible and/or economically viable?

- ◉ Yes
- ○ No
- ○ No opinion

*Subquestion to question C15: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

> Allowing any type of data carrier from 1D barcodes to proprietary coding passing by 2D barcodes without any standard will strongly put at risk the readability by all the concerned actors. They will imply specific readers able to handle all existing carrier and constant up date. It is not proven that such readers are existing and updatable and even if this was the case, the cost of such readers will be extremely high for a deployment of this geographic importance.

C16. Would you like to add any comments or suggestions on the choice of the allowed data carriers?

Text of 1 to 1500 characters will be accepted

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A single data carrier should be the most effective way to ensure the
interoperability of such traceability system at a European level; a 2D
barcode complying with existing standard such as GS1 allows all the producers
and manufacturers to interface with the system supporting European level
developments.

Even if a single data carrier is said to be offering insufficient flexibility
in view of different requirements, any small or medium size company implied
in such traceability project should be able to handle such standards. A
secure traceability system at a National or European level cannot be designed
as completely flexible. Actual traceability and regulations requirements are
already not so flexible and were implemented with success by all operators.
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Questions on the allowed delays in reporting events

* C17. Out of the three options for the allowed delays in reporting events outlined in the Inception Impact Assessment, which one do you consider most suitable for operating the traceability system from your perspective:

- ● Option D1: real-time (or limited delay – max. several minutes – reports)
- ○ Option D2: once daily reports
- ○ Option D3: once weekly reports
- ○ No opinion

* C18. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1, which envisages real-time reporting (or limited delays of maximum several minutes), would be particularly efficient to track products in transit as it would avoid duplicating scanning operations (e.g. by both a dispatcher/recipient and a transport operator?

- ● Yes
- ○ No
- ○ No opinion

* C19. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1 (real-time or limited delays of maximum several minutes) would support effective realtime risk analysis so that controls by competent authorities can be better targeted on illicit trade?

- ● Yes
- ○ No
- ○ No opinion

* C20. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that the once-daily frequency of data uploads provides for important cost savings for the economic operators as compared to the option of real-time reporting (or limited delays of maximum several minutes)?

- ◉ Yes
- ○ No
- ○ No opinion

Subquestion a) to question C20: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of real-time (or limited delay of maximum several minutes) reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?
Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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Real time option versus once-daily reporting would have estimated additional
cost impact of 12 to 15% of the operating traceability system cost.
The average likely increase in the cost of a pack of product will be close to
1€/1000
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Subquestion b) to question C20: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of once-daily reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?
Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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The average likely increase in the cost of a pack of product will be close to
0.2€/1000
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* C21. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that the once-weekly frequency of data uploads provides for important cost savings for the economic operators as compared to the option of once-daily reporting?

    ◯ Yes
    ◉ No
    ◯ No opinion

*Subquestion to question C21: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of once-weekly reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate.)?
Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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We estimate that the reduction of cost generated by the once-weekly option
instead of the once-daily option is neglectable, because most of the
operational charges necessary for a fluid daily workflow are already in place
in the weekly workflow. Only marginal peak of saturation can generated
additional costs, and models of distribution in European countries limits
this risk.
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C22. Would you like to add any comments or suggestions on the choice of the allowed delays in reporting events?

Text of 1 to 1500 characters will be accepted

Questions on the method of adding a security feature

* C23. Out of the three options for the method of adding a security feature that are outlined in the Inception Impact Assessment which one do you consider most suitable for securing the product from your perspective?

- ◉ Option S1: affixing
- ○ Option S2: printing or integrating through a different method
- ○ Option S3: any method
- ○ No opinion

* C24. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that by broadening the range of available methods, it will be easier for economic operators (including small and medium enterprises) to obtain the necessary level of security in a cost-efficient manner?

- ○ Yes
- ◉ No
- ○ No opinion

* C25. How do you rate the importance for consumers of having visible security features on unit packs of tobacco products?

- ◉ Important
- ○ Rather important
- ○ Neutral
- ○ Rather unimportant
- ○ Unimportant
- ○ No opinion

* C26. Do you consider that enabling individual consumers to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones) would bring added value to the effectiveness of the tracking and tracing system?

- ◉ Yes
- ○ No
- ○ No opinion

C27. Would you like to add any comments or suggestions on the choice of the method of adding a security feature?

Text of 1 to 1500 characters will be accepted

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The security feature must be a combination of a tamper evident physical
device and smart digital traceability system to deter manipulation attacks of
the physical device, provide visual authentication and ensure traceability
with multi level control operated by standard readers.

Only high security tamper evident labels embedding and combining high visual
security features with digital application can fulfill the requirements; they
have to be applied on production lines with standard low cost application
machine at production speed without interfering with production management
system.

Communication, training, education, control methods and all usages of the
security solutions should be as homogenous as possible to provide best
efficiency and ROIs.
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C28. Please upload any additional comments on the subject of this consultation (max. 5 pages)

Contact

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