

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 distributors 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 other organisation, please specify

Text of 1 to 800 characters will be accepted

Government owned company.

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 response 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)

A9. If you fall under respondent group **h**) above, please indicate your main area of activity:

Text of 1 to 800 characters will be accepted

Portuguese Mint and Security Printing Office.

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

Imprensa Nacional - Casa da Moeda, S.A.
Av. António José de Almeida, 1000-042 Lisboa

██████████
██████████

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

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

* 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 than option A2
- No opinion

* 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

Member States should have the independence to choose the model that best fits its governance model, ensuring that information is accessible to all entities, as described in the policy.

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

All the information is centralized. As such, the data must be replicated across multiple data storages, which implies a complex infrastructure, requiring a strong investment.

* 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

All information is stored in a single access point. If there is a problem, it is not possible to get the desired information.

* 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

**Subquestion to question C10: If other option is selected, please specify*

Text of 1 to 1500 characters will be accepted

Each Member State should be responsible for the information and its storage. Furthermore, each Member State should take responsibility for the products produced, traded or the traceability that takes place within its sovereignty area.

* 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 information must be placed in data storages, where there is a greater information flow.

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

Each Member State should be responsible for storing all information related to the products that reach its territory.

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 existing 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

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

The previous questions may possibly be incorrectly formalized. The issue is not the existence of multiple systems but what the standard for reading and accessing necessary information is.

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

We do not have enough information to accurately answer the question.

**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

* 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

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

The frequency of the reports should not take into account the costs but instead:

- Network latencies;
- Network resilience;
- Service availability;
- Data integrity and confidentiality.

In the previously described scenario, the communication between different Member States in real-time requires a complex infrastructure.

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

The security feature should be placed on the tobacco package only (pack, bag, etc.). The security feature must be a tax stamp since it can be applied to various surfaces versus materials.

C28. Please upload any additional comments on the subject of this consultation (max. 5 pages)

Contact

SANTE-B2-TOBACCO-CONTROL@ec.europa.eu
