

# 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

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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

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\*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 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)

## B. Respondant contact details

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## C. Consultation questions

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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

*\*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*

Both options A1 and A2 imply negligible consequences compared to the cost for the consumer of a tobacco pack.

*\*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*

Both options A1 and A2 imply negligible consequences compared to the cost for the consumer of a tobacco pack.

\* 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*

The generation of unique IDs should be done under State control. It should be linked to the security feature and data carrier:

- The States provide secure stamps to the industry
- The reading of stamp IDs is done by the industry
- The industry transfers to the States the WHO framework compulsory information

**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*

A centralized data storage provides for economies of scale, as all data can be stored by one market player.

\* 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 the queries will be addressed to one database, potentially slowing down access time.

\* 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*

Easier consultation and data management for authorities.

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*

Decentralizing data is irrelevant: new technologies provide the shortest interrogation times, no matter the physical location of the data storage. The best solution would be to have a centralized data base, easier to manager, plus decentralized redundancies.

On the other hand decentralized data storage allows more flexibility and different set up schedules for the building of the system among countries, probably a solution to come quicker to practical results against the big one that never comes. Subsidiarity could be kept in mind as well when deciding which scheme to adopt.

### 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

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

*Text of 1 to 1500 characters will be accepted*

A free system allowing any existing data carrier may cause several constraints:

- incompatibility with the readers at disposal
- the unawareness of authorities regarding certain codes

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*

A basic, common code should be applied to all tobacco products for interoperability (e.g. datamatrix the supply chain most fitted code as for Pharma european directive ). States should then have the possibility to add security features that might be specific provided a minimum level is required (see EU recommendation on regulation on passports).

### **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*

Queries on databases using IT cloud services have become very unexpensive with the development of the internet. The cost per pack should be negligible.

*\*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*

Business models routinely offer a free-of-charge consulting fee taking into account a global invoicing model of fee per item (pack) for global services: implementation of traceability and security features, with 24/7 database access.

\* 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*

Business models routinely offer a free-of-charge consulting fee taking into account a global invoicing model of fee per item (pack) for global services: implementation of traceability and security features, with 24/7 database access.

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 most frequent data exchanges are not limited by any technical constraints. Mobile data costs have dropped over the last decades.

### 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 features, the unique ID and the data carrier are the key fundamentals of the solution, enabling the industry to reach compliance. To avoid depending on the industry on one side and doing by substitution instead of just controlling the industry on the other, the only viable solution is to supply the data carrier with the unique ID and the security features to the industry: a stamp to affix. The reading and interfacing of those unique IDs with the information system of the industry should be made compulsory to the industry under their responsibility to deliver the information required by the WHO protocol and the European directive. The root of the system is government controlled while the compliance implications are industry born: reading, interfacing, reconciling. The stamp based solution is compatible with a proper management of imports as tobacco producers are familiar with applying stamps for export. Those selling into EEC will have to provide with the supplementary information made compulsory by the new directive like any producer within Europe. Simple.

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



## Contact

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