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

A5. If you fall under respondent group **d)** above, please indicate your main area(s) of activity:

- ☐ Importer
- ☑ Distributor
- ☑ Wholesaler
- ☐ Warehouse operator
- ☐ Other

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

* 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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Economic operators should be allowed to continue using existing systems and
equipment across the EU and should be able to choose the solution provider
that meets their needs. Otherwise; the costs would be higher, possibly
prohibitively so for smaller companies. It would also render compliance by
the 20 May 2019 deadline impossible.
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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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It is impossible to estimate the likely increase in the cost of a pack under
the third party solution as:
(1)        there is currently no clear concept of what this option would look
like, in particular regarding the future obligations of the trade and of the
warehousing/transporting companies; and
(2)        there is no specification regarding the role and designation of
the third party.

Also, as a general rule, any third party involvement will increase 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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in every area of tobacco regulation (i.e. excise, ingredients, packaging),
accountability for compliance sits with the manufacturer. The notion that an
independent third party must operate (parts of) the traceability system in
manufacturers' factories is absurd.
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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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An independent data storage solution
 (1) hosted by an independent third party selected by each manufacturer,
 (2) approved by the Commission and
(3) audited by an independent operator; is the most appropriate option and is
compliant with the TPD
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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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. It seems almost impossible that one operator alone could manage this task,
given the timeframe and the sheer size of the project
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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

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If the option of geographic decentralisation of data storages is considered,
the relevant data on a given product should be placed in a storage per
manufacturer as the manufacturer is always known and will be apparent from
the unique identifier, which makes the selection of the appropriate database
more straightforward, and it also does not have the disadvantages associated
with the other options
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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

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

> GS1 EPCIS interface standards and GS1 Application Identifiers (AI's) are already being used by economic operators involved in the distribution and sale of tobacco products in the EU. These standards and AI's will continue to be the 'universal language' of the system.
> It is important to note that these standards and AI's enable interoperability while leaving economic operators the freedom to choose the most appropriate technology according to their needs.

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

> On the choice of the allowed data carriers (C16), the data carriers that will be used in the TPD-compliant system being rolled out by the industry will be displayed in a DotCode. A Dotcode is a form of data carrier capable of holding a large amount of information that can be printed at high speeds and which occupies only a small print area. It was developed in response to the unique challenges faced by high-speed manufacturing, such as those experienced by the tobacco industry.
> It is non-proprietary and can be adopted by any manufacturer. As it is in the process of being approved as a GS1 standard; the accessibility and accurateness of the captured information is guaranteed.
> Moreover, the DotCode is machine-readable to allow the linking of packs to cartons so that they can be tracked in cartons/master cases/pallets without unpacking.
> For master case and carton tracking, GS1's internationally recognised serialisation and data carrier standards will continue to be used (SGTIN standards to create the serialisation number, EAN-128 and 2D DataMatrix to hold the serialisation number).
> The DotCode will appear on the bottom of the pack. This will enable every pack to be scanned as it moves along the production line and therefore allows aggregation of the packaging units; i.e. linking them to cartons/master cases /pallets.

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

> The likely cost increase of real-time reporting is impossible to quantify throughout the entire supply chain (subquestion a to C20). In any case, requiring this would add huge complexity both technically and process-wise for thousands of distributors across the EU. The definition of real time can actually become ambiguous as orders can be prepared and scanned the night previous to shipment. In these circumstances, is real time when the scanning takes place or when the shipment happens? Many of today's scanning equipment are based on docking stations. It is only when – after a certain time – the scanners are docked that the information is synchronized.

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

> The likely cost increase of once-daily reporting is also impossible to quantify throughout the entire supply chain (subquestion b to C20) and will vary from market to market due to the different distribution landscape. France, Spain and some others have one single licensed distributor which is highly automated. Other markets like Germany and the UK have thousands of distributors and wholesalers varying in size with either no or minimal technical and automation. These businesses will have to go through a technical development phase and new changes in business practices. This will need to be supported by their governments as ultimately the Member State governments will have the responsibility of informing all parties of the new legal requirements and be available for addressing queries.

* 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

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

> As the unique identifier is genuinely unique and 100% fool-proof, it
> constitutes an ultimate guarantee to consumers/and or enforcement authorities
> that want to check the veracity of their product, using a mobile phone or the
> internet.

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

Contact

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