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

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Bundesdruckerei GmbH offers IT security solutions for private companies,
governments and public authorities. The company's technologies and services,
all "Made in Germany", protect sensitive data, communications and
infrastructures. The solutions are rooted in the secure identification of
citizens, customers, employees and systems in both the analogue and digital
world. The company captures, manages and encrypts sensitive data, it produces
documents and verification devices, develops software for high-security
infrastructures and supplies passport and ID card systems, as well as
automated border control solutions.
For more information, go to: www.bundesdruckerei.de
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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

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Bundesdruckerei GmbH
Kommandantenstr. 18
10969 Berlin
GERMANY
████████████████████████
████      ██████████████████
█████████████████████
www.bundesdruckerei.de
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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 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

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

* 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

> Bundesdruckerei has been operating a TPD-conform pilot project with stakeholders of the whole supply chain since 2015. The focus is the cost efficient implementation under consideration of existing standards. A basic result is that the needs of individual industry stakeholders (manufacturer, wholesaler, distributer, retail) differ. Thus, there is the necessity of defining a technical framework permitting the implementation of several solutions for the respective segments. This framework ensures interoperability. Restricting the Governance Model to a solution operated by the industry or by a third party would decrease possible solutions to the detriment of individual stakeholders and prevent competition between solution providers. Hence, we support a Mixed Governance Model. This should meet the stakeholders' needs while adhering to a minimum technical standard defined by the EU Commission and allow fair competition. In this model, each industry stakeholder is individually responsible for the implementation and operation of tobacco product tracking solutions. Relevant is if the independent data storage operator shall be responsible for monitoring the supply chain or if it should carry out the required data analyses at the commission of the member states which, in turn, are then responsible for controls. It has to be defined if the manufacturer could then be the contracting entity or if the member states would not have to assume this role to ensure truly independent controlling.

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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see attachment
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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

* 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

> see attachment

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

> Both storage concepts are suitable to fulfill the requirements of TPD. Due to availability and performance needs, which have not been specified, the concepts can be regarded as being equally suitable, provided that the respective system architecture is in place. Differentiation of the concepts from the cost structure aspect depends on the degree of decentralisation and on the underlying criteria for distributed storage implementation. If the decentralisation would lead to identical product information being stored in multiple databases, then central data storage would be beneficial from the data maintenance cost aspect. This would automatically bring disadvantages to all industry stakeholders, obliged to observe one data and communication standard. This might mean cost disadvantages for individual stakeholders since tracking and tracing systems have already been established in some cases and would have to be adapted accordingly. Product-related decentralisation was the best solution in the pilot project. This ensures that all relevant information on a product is held at one location to avoid gaps in product traceability. The challenge for wholesalers and distributors is to write the data into the correct database. There is the need to determine what requirements the member states' national supervisory authorities place on the information service as far as traceability is concerned. An adequate system architecture can be deduced after definition of utilisation aspects.

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

see attachment

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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The data carrier aspect was discussed intensively during the pilot project.
The requirements of each individual participant in the pilot project cannot
be met using one single allowed data carrier. This applies in particular to
unit packets. In view of existing aggregation processes, a data carrier can
be implemented for each individual aggregation level thanks to the logistics
processes already established. This results in three data carriers being
supported: GS1-128, Datamatrix and DotCode.
The costs arising from the respective decision on allowed data carriers in
the productive system vary considerably and depend on what systems are
already in place. A decision to use 2D bar codes, in particular, would lead
to increased investment requirements since lower-cost line scanner technology
would have to be replaced. Another important aspect to be considered when
choosing the allowed data carrier is the importance of avoiding proprietary
technologies. The data carriers must conform to a universal standard in order
to allow competition between various solution providers. Furthermore,
definition of the structure of the UID represented by the data carrier is
essential for ensuring the necessary interoperability. In this respect, the
SGTIN proved its effectivity at the package level in the course of the pilot
project.
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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

* 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

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Until the final purpose and usage of the system has been defined, it is
difficult to provide answers concerning time delays in the representation of
the tracing system in comparison to representations in the individual systems
operated by industry stakeholders and the real goods movements.  If the
tracing system is only expected to provide a report on goods movements that
have already taken place, enabling retrospective reviews with the objective
of making decisions on reactive measures, then delays of a day or even a week
are acceptable. If the data on the system are to be used for active control
measures, then all event data indicating a change in product location or
ownership will have to be available almost in real-time. In this case, delays
of a few hours are acceptable in our opinion.
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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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By virtue of the current situation in Germany we can conclude that the
security concept implemented with the tax stamp has proved to be suitable for
eliminating forged products from the market. In principle, this solution
combines a security concept with a consumer taxation solution and involves
all stakeholders in the business, the control institutions and even
consumers. As a result, a powerful element for combating illegal products
within legal trade which is known and accepted in everyday use is already
available. From these aspects it can be deduced that Article 16 will be
implemented in Germany by the application of tax stamps. Alternative
solutions that take alternative methods of applying a security feature into
account are needed for those markets in which tax stamps are not a statutory
requirement. Implementation of the TPD will add a second mechanism to this
already established security mechanism, namely traceability by means of a
unique identifier on every package. In our opinion it is useful to involve
the consumer as an active participant.
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C28. Please upload any additional comments on the subject of this consultation (max. 5 pages)

4f66ef21-7e2f-4fad-802e-050ae80a9019/Comments_20161104_en_final_Anhang.doc

Contact

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