

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 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

Inexto SA
Avenue de Dapples 7
1006 Lausanne
Suisse

[Redacted contact information]

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

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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

**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

If industry-operated, the estimated increase in running cost is roughly € 50.00 per million sticks (or 0.1 Euro- cents per pack).

The CAPEX required for this approach is estimated at 500'000 Euros per production line. This figure corresponds to 0.1 Euro-cents per pack and is based on a 5-year depreciation schedule for equipment in a mid-speed machine environment.

Some manufacturers have already installed serialization and aggregation equipment; therefore, the required additional hardware costs should be reduced assuming the existing equipment would be compliant. Others who haven't yet invested in a system would benefit from a competitive market.

The largest cost impact will likely be in the implementation of supply chain tracking. It is difficult to come with a definitive cost analysis as the supply chain networks differ from market to market and legitimate actors can also vary over time. Using Open Standards will increase competition, through a larger number of solution providers, and thereby lower costs.

Furthermore, it is likely that an entire supply chain will not be able to effectively implement any solution that will differ by manufacturer and/or by Member State. The only feasible option for effective supply chain tracking is to base the full scheme on Open Standards, such as GS1, so that economic operators will be able to competitively select appropriate equipment while ensuring full compliance with requirements over both the EU and its Member States

**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

Option A2, when compared with option A1, must be similar with respect to hardware and system capital investments. However, from an operational perspective, a third-party operated system implies a direct increase in personnel costs; operators working redundantly and in parallel with industry personnel. The installation and operation of equipments on the production lines by third parties operators should also increase the price as these operators will probably include provisions for liabilities in case of impact of the equipment on the operations and production of tobacco manufacturers and supply chain operators

* 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

- Elements critical to the entire system's integrity (i.e.: serialization, data transmission, management, storage) should be managed by independent providers.
- Code generation should be under the control of governments, or controlling / supranational entities through licensing/ authorization mechanisms
- Codes should be generated directly on production lines, to avoid the transmission of pre-established lists of codes, which would constitute a threat to the integrity of the system
- Selection, standardization and operation of hardware for printing, scanning, and aggregation, could be the responsibility of manufacturers and distributors. These hardware elements cannot pose a risk to the system's integrity and the allocation of responsibility would best ensure (i) the hardware is operable under production requirements (e.g. machine speeds), (ii) a faster implementation and -(iii) open and competitive market of equipment providers (iii) that liabilities are clearly defined between solution providers and manufacturers.

The full system should be regularly audited by the public authority or an independent auditor appointed by that authority.

The governance model should mandate Open Standards (e.g. GS1, ISO) and rules that ensure interoperability within/between countries (including 3rd party imports), amongst legitimate supply chain actors, and across industries.

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

Centralized data storage across EU Member States will be more efficient and practical for controlling authorities than a system decentralized by Member States. In addition, since the same production lines and warehouse networks typically supply a large number of countries, decentralization by country or product will introduce significant complexity to both data management and analysis. This centralized configuration will also best leverage economies of scale.

We recommend to segregate data by manufacturer. Specifically, one central database per manufacturer, coupled with the ability for applicable government agencies to conduct queries and analyses across all manufacturer databases. This configuration avoids introducing risk by the co-mingling of sensitive market information from each brand owner, thereby avoiding breaches of confidentiality or anti-competition issues. This approach will also better facilitate the management of access by each brand owner to its respective product data (i.e.: on a read-only basis).

Article 15.8 of the TPD already addresses this topic with clear and operational guidelines.

*** 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

A decentralized data storage configuration introduces greater performance risk as the system will rely on a larger number of IT components (e.g.: database servers, network, etc.) than the centralized approach. Downtime to any one of these numerous IT components is likely to have a negative impact on the overall ability of the system to respond to queries.

* 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

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 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

In the case of various data carriers, it is essential to reference GS1 standards. It allows for both flexibility and due process. GS1 manages any modification to its standards (including the data carriers) to limit the impact on installed systems. To refer to GS1 B12 Policy: The GS1 Global Standards Management Process (GSMP) is the mechanism to approve the adoption of new technology for the GS1 System. For Work Requests to add an AIDC data carrier that is not currently used in an AIDC Application Standard to an existing or new AIDC Application Standard and for it to be used exclusively in place of a currently approved GS1 data carrier, an evaluation based on the following conditions is required as a part of the GSMP approval—Technology is freely implementable to the best of our knowledge—A technique must be available and allocated exclusively to GS1 in order to enable unambiguous identification of GS1 data structures—Tested to ensure it will not substantially disrupt scanner or reader performance for existing AIDC data carriers—The new AIDC data carrier option can be implemented exclusively in 90%+ of installed scanner/reader locations for a given Operative Scanner Environment as defined by the GS1 General Specifications without significant disruption to the performance of existing AIDC data carriers. The GS1 MB and General Assembly (GA) may decide to make an exception to the 90%+ minimum by establishing a Sunrise Date to reach the minimum and deploying Program to reach that goal

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 system should provide for the usage of any GS1 data carrier, including the GS1 Dotcode. Dotcode is under final ratification by GS1 and is the only known carrier compatible with direct marking on high speed production lines. The governance model should not impose a single type of data carrier, as different packaging types / configurations might have different constraints (e.g.: reading distance, size, positioning, etc.) and require different carriers.

We also believe the regulation should provide for systematic marking of the unique identifier directly on the products. Marking the code only on a label (or stamp) will be less secure than directly marking the product because the label or stamp can be removed from the product and the coded information lost. In case of stamps, the pack's unique identifier could be paired with the stamp's identifier, as a means to better control excise rights

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 amount of data to be transferred being same for the three options, we tend to believe that a continuous upload of data will not be more expensive than once-daily or once-weekly. By spreading data transmission over a longer period, the solution would allow for lower network capacity and reliability.

We believe that the solution should accept a delay of a few hours in order to cope with potential network issues, especially in locations where network connectivity will have to be established through a mobile network.

**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 amount of data to be transferred being same for the three options, we believe that the cost will be close to the real-time option.

* 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

While the total volume of data to be transmitted will be the same as in the other option, sending that data once a week would require an increase in both the reliability and bandwidth of the network. For these reasons, we believe that this solution will be more expensive than the alternatives.

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

Real-time, or near real-time, reporting will be more efficient for the tracking of product and will enable a more efficient control by law enforcement authorities, contingent on accurate and comprehensive data. It will also increase the integrity and security of the systems as the data will be transmitted immediately to the secure data repository.

We believe it will not increase the cost as it will require lower bandwidth capacity and provide for a better stability of data transmission, spreading volumes of data transmitted across time.

However, true real-time reporting requires a network with high quality and availability. Such networks are not consistently available for all economic operators. A near real-time reporting regime, whereby real-time is retained as a best-effort target but also where data transmission delays up to 4 hours following the scanning event can be managed, could offer an acceptable compromise.

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

Experts recognize that visible features cannot assure authenticity control by untrained citizens. Counterfeit items in the form of tax stamps, banknotes, etc. don't need to be perfect, just 'good enough' to trick the untrained eye. We consider it essential to leverage the code, as required by Art 15, by extending its functionality as the visible feature required by Art 16. In this manner, untrained citizens can participate in the process by performing this control using dedicated internet tools or mobile applications. We recommend combining this visible feature with forgery proof Digital Fingerprinting ("DF"). DF relies on two products, appearing identical to the naked eye, being discernably different when resolved in their structure to sufficient detail. DF can be seamlessly implemented on a production line and at all production speeds. Combining the visible code with the pack's DF creates an unforgeable, innate and indelible digital seal linking a pack's authenticity to its identity. DF minimizes security risks, added costs and additional burdens from the handling, storage and insurance of traditional security features. It is not in opposition to existing tax stamps with embedded visible/invisible security features. DF technology is fully compatible with Art 16 and with those governments having no stamps whatsoever. We welcome the Commission's approach to encourage the use of modern technologies and believe DF technology is well-positioned when considering new technologies

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

Contact

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