

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 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

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 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

We consider A1 to be the most cost effective and cheaper than A2, as Option A2 will incur extra costs which can be avoided under option A1. Option A2 implies a duplication of infrastructure, for example on line level operations (Printing, Vision system, Control), and management activities. Option A1 leverages the expertise and knowledge of the manufacturers, who know best how to run their production system, which includes marking and tracking of products throughout their internal Supply Chain (SC). Each manufacturer has a different SC setup, and an in depth knowledge of all relevant systems is required. A third party would need to put a lot of effort to build up basic knowledge, set aside the extra costs related to installing and operating extra infrastructure. Option A1 limits the extra cost to installing an adequate control and verification system (to be determined by the relevant authorities) and leverages the expertise of the manufacturers.

The only fair statement about extra costs at this stage, without having any detail on the final solution, is that A1 will limit the cost to an absolute minimum, and that it will be a fraction compared to the cost of Option A2. This statement is based on the fact that A1 leverages an existing system and equipment in use by the manufacturers, not an 'extra' third party solution. This allows for a comprehensive governance model, with reduced interfacing and connectivity requirements.

**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

We consider A1 to be the most cost effective and cheaper than A2, as Option A2 will incur extra costs which can be avoided under option A1. Option A2 implies a duplication of infrastructure, for example on line level operations (Printing, Vision system, Control), and management activities. Option A1 leverages the expertise and knowledge of the manufacturers, who know best how to run their production system, which includes marking and tracking of products throughout their internal Supply Chain (SC). Each manufacturer has a different SC setup, and an in depth knowledge of all relevant systems is required. A third party would need to put a lot of effort to build up basic knowledge, set aside the extra costs related to installing and operating extra infrastructure. Option A1 limits the extra cost to installing an adequate control and verification system (to be determined by the relevant authorities) and leverages the expertise of the manufacturers. The only fair statement about extra costs at this stage, without having any detail on the final solution, is that A1 will limit the cost to an absolute minimum, and that it will be a fraction compared to the cost of Option A2. This statement is based on the fact that A1 leverages an existing system and equipment in use by the manufacturers, not an 'extra' third party solution. This allows for a comprehensive governance model, with reduced interfacing and connectivity requirements.

* 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

- Option A1 is for cost efficiency reasons the most viable option (for rationale, see responses to sub questions C4)

- Given the TPD planned timeframes, and based on our experience with deploying a large scale system involving different stakeholders, we also believe Option A1 to be the only realistic option from a timeframe perspective.

Option A2 requires a third party to assess each individual Manufacturing site, Distribution Center, Wholesale Site and other impacted Economic Operators. An adequate assessment of the best system to be installed, and how to adapt it to each individual site would be an essential but time consuming project activity for the chosen third party(s). We believe Option A2 would require a review of planned implementation as currently foreseen by TPD. Compared to Option 1, Option A3 will also lead to more complexity and will equally lead to a more lengthy project plan. This would require a review of the planned implementation timeframe as currently foreseen by TPD.

- Option A2 and A3 also lead to a more complex legal framework, as a third party would be required to perform activities on Manufacturing lines and sites. This may incur liability and other issues to be addressed.

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

We believe the most effective concept would be based on what is described in the Inception Impact Assessment doc as 'independent decentralized data storage by product' (or producer).

- Each of these databases would be fed, through a "data broker", by each relevant Data Supplier of that product (Manufacturers, and DC operators),... This concept could lead to 5 (or more) different databases: one database containing the information of products manufactured by each of the 4 large manufacturers, and one (or more) for the 'Other Manufacturers', providing for data segregation between manufacturers. A cloud based setup for these 'Other Manufacturers' may provide further economies.

- Each Data user (EC or MS authority body) would be able to perform their own queries, or download information from these 5 (or more) databases, depending on its relevancy.

Our described decentralized concept provides for economies of scale, and eliminates the need for a central registry.

Given market size (amount of packs) and Supply Chain complexity, a Centralized storage approach would create a massive database. Compared to our suggested independent decentralized approach, it would lead to more complexity and substantially slower response times. Moreover, it would not be the best basis for one of the core purposes of the system: Providing each EC and MS authority body with access to relevant product and traceability information. Please refer to Response C28 for more information.

*** 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

The Market size and complexity of the supply chain (amount of manufacturers, distributors and wholesalers) for tobacco products indicate that the concept of one central database will represent higher risks in terms of time required to access data and potential downtimes, compared to a decentralized storage. The size of one centralized database and the amount of anticipated queries by the different Data Users (EC and MS) compared to a decentralized approach, increases the risk of poor response times.

A decentralized database approach divides the impact of a single point of failure. At peak moments, when simultaneous queries can be anticipated, there is a higher risk of down times, compared to a decentralized data storage approach.

Moreover, since the Data User queries to the database(s) will mostly be product based (which will have a unique identifier), it makes economic and functional sense to envisage a decentralized data storage approach, based on product.

In general, response times are dependent on the size of the database. In case of down time, the time needed to get 'back to operations' will increase in case of a larger size database.

* 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

██████████ suggests to adopt a decentralized data storage approach per product. It is based on centralizing all relevant data of a product in one database. This makes the feeding of the database by the Data Suppliers (Manufacturers and DC operators) simple, as there is only place. It also makes queries by the Data Users (EC and MS authorities) simple, since the core identification is based on the product (determined by the Unique Identifier), which is stored in one place.

The physical location of the storage is less relevant, since feeding data to the database can come from any place inside EU (or even outside in case of manufacturing for example). The queries can come again from any Data User (EC or MS authority). All 3 suggested storage locations seem difficult concepts to maintain given the complexity of the Data Suppliers and the Data users. Most Data Management Service Providers will have the experience and adequate infrastructure to determine where and how to best store the data. A place like Brussels, Paris, Berlin, as central location with good network connectivity and capacity could make sense.

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

As a System integrator, [REDACTED] has been involved in different projects spanning different industries. We actively promote the use of Open Standards, as we consider it a cornerstone for successful projects. Given the amount of players active in the tobacco market, a free system allowing any data carrier could complicate interoperability, and would not lead to cost efficiency. We believe Option C2 to be the most preferential for operating the Traceability system, as it provides the right balance and flexibility.

- 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 vast majority of economic agents active in the tobacco sector already work with GS1 standards, which we consider the best foundation to compose a cost effective and interoperable system.

- GS1 EPCIS standard enables trading partners to efficiently share information about the physical movement throughout the supply chain - from business to business and ultimately to consumers. We recommend this standard for ensuring compatibility between T&T systems.
- GS1 Linear barcodes (EAN 128) and Datamatrix can be used for higher levels of (aggregated) stocks of products (cartons, cases, pallets) .
- The tobacco manufacturing lines work at speeds which do not allow data matrix as a reliable data carrier for pack/SKU level. We recommend Dotcode standard instead. Dotcode is a proven data carrier which can deal with high-speed manufacturing environments, and can hold sufficient amount of information.

Questions on the allowed delays in reporting events

* C17. Out of the three options for the allowed delays in reporting events outlined in the Inception Impact Assessment, which one do you consider most suitable for operating the traceability system from your perspective:

- ☐ Option D1: real-time (or limited delay – max. several minutes – reports)
- ☒ Option D2: once daily reports
- ☐ Option D3: once weekly reports
- ☐ No opinion

* C18. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1, which envisages real-time reporting (or limited delays of maximum several minutes), would be particularly efficient to track products in transit as it would avoid duplicating scanning operations (e.g. by both a dispatcher/recipient and a transport operator)?

- ☒ Yes
- ☐ No
- ☐ No opinion

* C19. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1 (real-time or limited delays of maximum several minutes) would support effective realtime risk analysis so that controls by competent authorities can be better targeted on illicit trade?

- ☒ Yes
- ☐ No
- ☐ No opinion

* C20. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that the once-daily frequency of data uploads provides for important cost savings for the economic operators as compared to the option of real-time reporting (or limited delays of maximum several minutes)?

- ☒ Yes
- ☐ No
- ☐ No opinion

**Subquestion a) to question C20: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of real-time (or limited delay of maximum several minutes) reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?*

Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

We assume that many of the Small to Medium economic agents are not capable to deal with real time processing, nor do they have the necessary equipment. Given the amount of Small to Medium economic agents active in the Supply Chain, the total investment cost would be substantial, and impose issues to remain active in case real time processing would be imposed. They would need to drastically change their operational modus and processes. The actual cost and effort for operating in real time may not justify the investment, given the actual volumes these individual agents handle.

- The economies of scale/efficiency gains will not outweigh the possible cost of duplication of scanning operations in these small to medium scale environments.

- Although we think that real time reporting could support effective real time risk analysis, any efficiency gain would be hard to quantify or predict. Therefore we think it does not justify the total investments a real time reporting setup would require.

Without having any detail on the final solution, we can't make any fair estimation about likely cost increase at this stage, given the supply chain diversity and complexity.

**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

We assume that only a small fraction of the (Small to Medium) economic agents would not be capable, or not have the necessary equipment, for once-daily reporting. It would not have any drastic impact on their operational modus or processes either. Given the difference in distributor landscape between Member States, a country by country assessment makes sense to determine the best framework and measures (licensed distributor system in for example Spain and France vs the diverse market of distributors in Germany vs small markets like Belgium and Lithuania).

Once daily reporting seems realistic to achieve throughout the Member States, and the related investments can be justified by the overall objectives TPD is trying to achieve.

Without having any detail on the final solution, we can't make any fair estimation about likely cost increase at this stage, given the supply chain diversity and complexity

*** 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

Without having any detail on the final solution, we can't make any fair estimation about likely cost increase at this stage, given the supply chain diversity and complexity

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

██████████ is involved with many governments and different industries to discuss the potential of Authentication and T&T systems as key tools to reach their goals. We are equally studying surveys and interviews to better understand the underlying drivers of each economic agent. We see a general trend which all actors share when it comes to consumer products: Governments, Law Enforcement, Regulators and Consumers want transparent, reliable and 'trusted' Track & Trace and product data. It is also proven that, the more product verifications are performed, the more likely you will detect counterfeit products and spot illicit trade. Worldline strongly believes in the power of digital security features (ex. unique codes printed directly on a pack or fingerprint). Paper-based stamps or labels affixed to a pack are often counterfeited, and create a false sense of security, as it may only provide information about the label itself, not the product. Digital security features provide access to T&T and product data to a broad group of economic agents, all of which can contribute to the battle against counterfeit and illicit trade. Systems which are based on applying digital codes directly on products can gain a deep insight into the movements of legal (and illegal) goods when combined with consumer engagement: Today's smartphone and App technology allow citizens to check the authenticity of products they intend to purchase.

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

a624d229-d2a9-40a4-9384-768172f0cd49/Worldline_Concept_for_EU_TPD_Traceability_solution.pdf

Contact

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