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 other organisation, please specify

Text of 1 to 800 characters will be accepted

```
blue-infinity is an IT consulting and services company.
Our clients are international companies active in the following sectors:
 - Public administration
 - Banks and financial institutions
 - NGOs
 - Luxury industry
 - Pharmaceutical industry
 - FMCG sector (tobacco included)
 - Others

blue-infinity has 15 years expertise in traceability solutions and
consulting, in the context of the tobacco industry. We later extended our
activity into pharmaceutical industry. We are a provider of solution
including serialization to tracking and tracing. blue-infinity is also a data
storage provider thanks to its hosting facilities.
```

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

```
500 employees working at blue-infinity
```

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)

A9. If you fall under respondent group **h)** above, please indicate your main area of activity:

Text of 1 to 800 characters will be accepted

```
blue-infinity is an IT consulting and services company.
Our clients are international companies active in the following sectors:
 - Public administration
 - Banks and financial institutions
 - NGOs
 - Luxury industry
 - Pharmaceutical industry
 - FMCG sector (tobacco included)
 - Others

blue-infinity has 15 years expertise in traceability solutions and
consulting, in the context of the tobacco industry. We later extended our
activity into pharmaceutical industry. We are a provider of solution
including serialization to tracking and tracing. blue-infinity is also a data
storage provider thanks to its hosting facilities.
```

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

```
Name: blue-infinity SA
Address: route des jeunes 35, 1227 Carouge (GE), Switzerland
██████████████████
████████████████████████
```

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)

3ee095b0-8f89-4e19-93cf-7d02036bdbbe/Registre_du_commerce_b-i_GE_mars_2016.pdf

* 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

```
In all solutions, manufacturers will have to master/monitor their supply
chain and therefore implement tracking for their needs. They have a strong
interest to find an efficient and effective solution (due to legal
constraints) and will care about the related costs.

A third party will not have the same objective, duplicating the costs.
```

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

```
In all solutions, manufacturers will have to master/monitor their supply
chain and therefore implement tracking for their needs. They have a strong
interest to find an efficient and effective solution (due to legal
constraints) and will care about the related costs.

A third party will not have the same objective, duplicating the costs.
```

* 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

```
Production environment constraints cannot afford this complexity without up-
time impact and associated costs. The solution should be based on open and
global standards such as GS1 and leave the choice of implementation to the
industry.
```

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

> The solution should be an EU wide solution as supply chains are transnational. Therefore, "decentralised data storage" viewed as country or product based is complex to achieve. Its therefore less efficient from a central EU governance point of view. Customs and Authorities should have the adequate tools to investigate data on purpose.
>
> Economy of scale is achievable if the "decentralised data storage" take logistic providers and manufacturers into account. This forcing them to have automated and audit-proof data exchange (like the banks).
> Duplicating the storage is additional investment. Standardisation the queries needed represent a valuable alternative, system integrity can be audited by independent parties.
>
> A centralised data storage will be complex to maintain and cots more, but centralization of the analytical tools for EU state members and authorities will reduce costs.
>
> Our perception of the centralisation of data (as well as country based storage) has been addressed on an ideological basis but not assessed technically. Based on our experience, the risk of failure of centralisation is huge, and the pharmaceutical industry's approach with regional storage does not take care of traceability (therefore cannot be compared in complexity).

* 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 central repository would be a single point of failure with respect to data access and performance.

* 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

Subquestion to question C10: If other option is selected, please specify

Text of 1 to 1500 characters will be accepted

> See C8 answers for details, the data should be split per manufacturer and/or logistics provider/solution provider.

* 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

```
The solution should be EU wide and consider transnational supply chain.
```

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

```
It would increase system maintenance complexity for a low value in terms of
solution's coverage/efficiency
```

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

```
Should be following standard as GS1 (dotcode, datamatrix, EAN) and adapted to
the context of the industry production constraints (line speed, warehouses
operations...)
```

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 believe the complexity and related costs relates to the data acquisition
and not to the data transmission.

Regarding factories, the system has to sustain high-speed and non-stop load,
suggesting a real-time capability as required.
Regarding supply chain, it's much slower than manufacturing the products,
therefore real-time achievable.
```

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 believe the complexity and related costs relates to the data acquisition
and not to the data transmission.

Regarding factories, the system has to sustain high-speed and non-stop load,
suggesting a real-time capability as required.
Regarding supply chain, it's much slower than manufacturing the products,
therefore real-time achievable.
```

* 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

```
We believe the complexity and related costs relates to the data acquisition
and not to the data transmission.
```

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

```
In general, we would say that the shorter the better, but the system has to
support network outages/service maintenance at all levels.
```

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

15

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

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

Contact

SANTE-B2-TOBACCO-CONTROL@ec.europa.eu