Case Id: d2d48aa0-68ad-40e3-bbe7-57dbcba4bb2d

Date: 09/07/2015 18:46:23

Targeted stakeholder 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.

This is a targeted stakeholder consultation. The purpose of this consultation is to seek comments from stakeholders:

- directly affected by the upcoming implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the new Tobacco Products Directive (Directive 2014/40/EU), or
- considering to have special expertise in the relevant areas.

In the Commission's assessment, the following stakeholders, including their respective associations, are expected to be directly affected:

- 1. manufacturers of finished tobacco products,
- 2. wholesalers and distributors of finished tobacco products,
- 3. providers of solutions for operating traceability and security features systems,
- 4. governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade.

Not directly affected are retailers and upstream suppliers of tobacco manufacturers (except the solution providers mentioned in point 3 above).

The basis for the consultation is the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFEA) in response to tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter the Feasibility Study). The Feasibility Study was published on 7 May 2015 and is available at http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf. The interested stakeholders are advised to review the Feasibility Study before responding to this consultation.

The comments received in the course of this consultation will be an input to the further implementation work on a future EU system for traceability and security features. In particular, the comments will be taken into account in a follow-up study.

Stakeholders are invited to submit their comments on this consultation at the following web-address https://ec.europa.eu/eusurvey/runner/trace until 31 July 2015. The web-based survey 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 or to upload (a) separate document(s) in PDF format up to the limit of total number of standard A4 pages (an average of 400 words per page) indicated in the question. Submissions should be - where possible - in English. For a corporate group one single reply should be prepared. For responses from governmental organisations, which are not representing a national position, it should be explained 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 consult the privacy statement). Participants in the consultation are asked not to upload personal data of individuals.

The replies to the consultation will be published on the Commission's website. In this light no confidential information should be provided. If there is a need to provide certain information on a confidential basis, contact should be made with the Commission at the following email address: SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu with a reference in the email title: "Confidential information concerning targeted stakeholder consultation on the implementation of an EU system for traceability and security features". A meaningful non-confidential version of the confidential information should be submitted at the web-address.

Answers that do not comply with the specifications cannot be considered.

A. Respondent details

*A.1. Stakeholder's main activity:
 a) Manufacturer of tobacco products destined for consumers (finished tobacco products)
b) Operator involved in the supply chain of finished tobacco products (excluding retail)
c) Provider of solutions
d) Governmental organisation
O e) NGO
f) Other
*A.1.b. Please specify:
i) Importer
ii) Distributor
☑ iii) Wholesaler
iv) Warehouse operator (unless part of 1a of 1bi, ii or iii)
v) Other

*A.2. Contact details (organisation's name, address, email, telephone number, 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



- *A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):
 - Yes
 No
- *A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.
 - cb4232dc-956b-43de-999e-ccb53b44950d/FeTaDis.pdf

B. Options proposed in the Feasibility Study

B.1. Please rate the appropriateness of each option for tracking and tracing system set out in the Feasibility Study in terms of the criteria listed in the tables below

B.1.1. Option 1: an industry-operated solution, with direct marking on the production lines carried out by tobacco manufacturers (for further details on this option, please consult section 8.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Somewhat appropriate Neutral Somewinappr		Inappropriate	No opinion
*Technical feasibility	0	©	0	•	0	0
*Interoperability	0	•	0	0	0	0
*Ease of operation for users	0	0 0		0	•	0
*System integrity (e.g. low risk of manipulation)	•	©	•	©	•	©
*Potential of reducing illicit trade	0	©	0	©	©	•
* Administrative/financial burden for economic operators	0	•	0	0	•	0
* Administrative/financial burden for public authorities	0	©	0	•	0	•

B.1.2. Option 2: a third party operated solution, with direct marking on the production lines carried out by a solution or service provider (for further details on this option, please consult section 8.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	•	0	0
*Interoperability	0	•	0	0	0	0
*Ease of operation for users	0	• •		•	•	0
*System integrity (e.g. low risk of manipulation)	0	©	•	•	0	0
*Potential of reducing illicit trade	0	•	0	•	0	•
* Administrative/financial burden for economic operators	0	©	0	•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	0	•

B.1.3. Option 3: each Member State decides between Option 1 and 2 as to an entity responsible for direct marking (manufacture or third party) (for further details on this option, please consult section 8.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Inappropriate	No opinion	
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	0	© © •		•	0
*Ease of operation for users	0	•	0	<!--</th--><th>0</th>		0
*System integrity (e.g. low risk of manipulation)	0	©			•	•
*Potential of reducing illicit trade	0	•			•	•
* Administrative/financial burden for economic operators	0	©	0	0	•	0
* Administrative/financial burden for public authorities	0			©	•	

B.1.4. Option 4: a unique identifier is integrated into the security feature and affixed in the same production process (for further details on this option, please consult section 8.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Inappropriate	No opinion	
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	•	0	0	•	0
*Ease of operation for users	0	•	0	•	•	•
*System integrity (e.g. low risk of manipulation)	•	•	•	•	•	•
*Potential of reducing illicit trade	0	•	0	•	•	•
* Administrative/financial burden for economic operators	0	•	•	•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	©	•

- B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
 - B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below

B.2.1. Option 1: a security feature using authentication technologies similar to a modern tax stamp (for further details on this option, please consult section 9.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Inappropriate	No opinion
*Technical feasibility	©	0	0	©	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0			0	•	
*System integrity (e.g. low risk of manipulation)	0			0	•	
*Potential of reducing illicit trade	0	©	0	0	0	•
* Administrative/financial burden for economic operators	0	©	0	0	0	•
* Administrative/financial burden for public authorities	0	•	0	©	0	•

B.2.2. Option 2: reduced semi-covert elements as compared to Option 1 (for further details on this option, please consult section 9.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Inappropriate	No opinion
*Technical feasibility	0	0	0	0	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0			0	•	
*System integrity (e.g. low risk of manipulation)	0	©	0	0	•	•
*Potential of reducing illicit trade	0	• •		0	0	•
* Administrative/financial burden for economic operators	0	•	0	0	0	•
* Administrative/financial burden for public authorities	0	©	0	•	•	•

B.2.3. Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection (for further details on this option, please consult section 9.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Somewhat appropriate Neutral Somewhat inappropriate Ina		Inappropriate	No opinion
*Technical feasibility	0	0	0	0	0	•
*Interoperability	0	•	0	0	0	•
*Ease of operation for users	0			•	•	
*System integrity (e.g. low risk of manipulation)	•			•	•	
*Potential of reducing illicit trade	0	0 0		0	0	•
* Administrative/financial burden for economic operators	0	©	•	•	•	•
* Administrative/financial burden for public authorities	0	©	0	•	•	•

B.2.4. Option 4: security feature is integrated with unique identifier (see Option 4 for traceability) (for further details on this option, please consult section 9.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Somewhat appropriate Neutral Somewhat inappropriate		Inappropriate	No opinion
*Technical feasibility	©	0	0	©	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0			0	•	
*System integrity (e.g. low risk of manipulation)	0			0	•	
*Potential of reducing illicit trade	0	©	0	0	0	•
* Administrative/financial burden for economic operators	0	©	0	0	0	•
* Administrative/financial burden for public authorities	0	•	0	©	0	•

B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

C. Cost-benefit analysis

C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	•	©	•	•	•	•
*The cost analysis presented in section 11.3.2 of the Feasibility Study	0	©	©	©	•	©

*C.1.1. If you selected	d option "Disagree" or "	'Somewhat disagree"	in the previous	question, please
upload your main rea	asons for disagreemen	t (max. 5 pages)		

D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16). When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities

operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.
*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)? a) A single standard provided by a relevant standardization body b) A public accreditation or similar system based on the minimum technical and interoperability requirements that allow for the parallel use of several standards; c) Another solution d) No opinion
D.2. Please upload any additional comments relating to the rules for generation of a serialized unique identifier referred to in question D.1. above (max. 2 pages)
*D.3. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)? ☑ a) Solution based on a single data carrier (e.g. 1D or 2D data carriers) b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers; ☐ c) Another solution; ☐ d) No opinion
*D.3.a. Please indicate your preferred data carrier and explain why Text of 1 to 400 characters will be accepted
No preference

^{• 32}d76b87-0ac9-499a-8d16-0d1aabbfcf97/Fetadis Position Paper T&T.pdf

*D.4. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?
a) System only operating with machine readable codes;
b) System operating both with machine and human readable codes;
C) No opinion
D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a
serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)
*D.C. Demandian the above in later and the control in a control in the control in
*D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?
a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
b) After a pack/tin/pouch/item is folded/assembled and filled with products;
C) No opinion

D.7. Please upload any additional comments relating to the placement of a serialized unique

identifier referred to in question D.6. above (max. 2 pages)

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	•	0	•	0	•
*Marking products with serialized unique identifiers on the production line	•	•	•	•	•
*Verifying if products are properly marked on the production line	0	•	•	•	0
*Scanning products upon dispatch from manufacturer's/importer's warehouse	0	•	•	•	0
*Scanning products upon receipt at distributor's/wholesaler's premises	•	•	0	•	0

*Scanning products upon dispatch from distributor's/wholesaler's premises	•	•	•	©	•	
*Aggregation of products	•	0	0	0	0	

D.9. In relation to question D.8. above, please specify any other measures that your organisation considers relevant Text of 1 to 1200 characters will be accepted
*D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which of the following solutions do you consider as appropriate (multiple answers possible)? a) A security feature is affixed; b) A security feature is affixed and integrated with the tax stamps or national identification marks; c) A security feature is printed; d) A security feature is put on the pack/tin/puch/item through a different method; e) No opinion
D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)
*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which of the following solutions do you consider as appropriate (multiple answers possible)? ☑ a) A single centralised storage for all operators; b) An accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory); ☐ c) Another solution ☐ d) No opinion
D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)
*D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)? a) Provider of solutions to collect the data from the manufacturing and distribution chain; b) Provider of data storage services; c) Another entity d) No opinion

- D.15. Please upload any additional comments relating to the development of reporting and query tools referred to in question D.14. above (max. 2 pages)
- *D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)?
 - a) Yes
 - b) No
 - C) No opinion

D.16.b. If no, please explain your considerations

Text of 1 to 800 characters will be accepted

Enabling the consumer to verify T & T would only improve the integrity if T & T obligations would also apply on Retail. Indeed if not, it will result and confusing system of responsabilities taken into account the missing link between Wholesale and consumer.

However, we are supportive that a unique identifier enables the consumer to verify the authenticity of the product

- D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)
 - · cd19aaca-2cad-411c-bcdb-51fc5dc83e6c/Fetadis Position Paper T&T.pdf

Contact

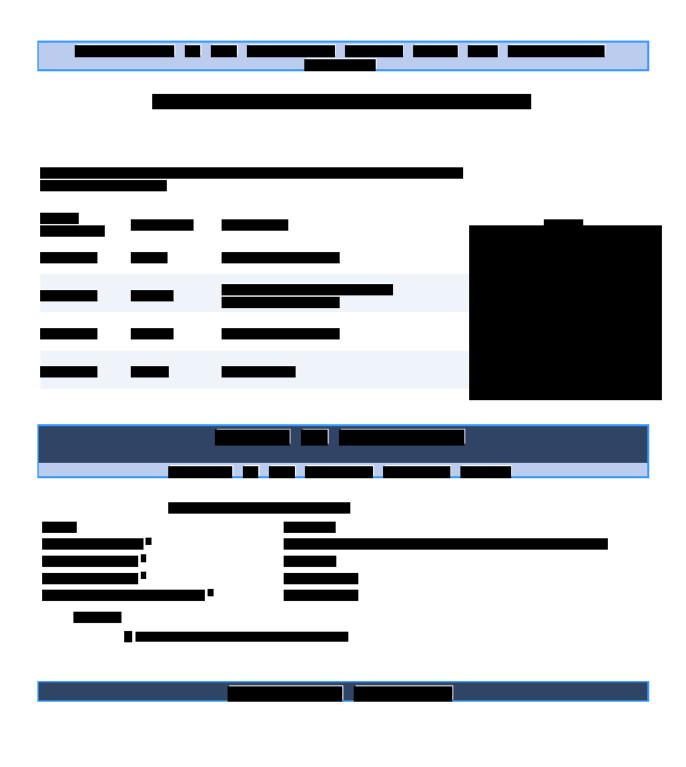
SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu





FEDERATIE VAN DE TABAKSDISTRIBUTEURS





Asb. Fetadis Vzw

Belgian Federation of Tobacco Wholesalers¹ Position Paper on Feasibility Assessment Regarding EU Systems for Tracking and Tracing of Tobacco Products (TPD – Art. 15)

A) General

- Fetadis has the firm conviction that the whole feasibility report has been written
 focusing on the potential impact of a T & T system primarily from the viewpoint of
 the tobacco manufacturers. Whereas art. 15 of the TPD impacts all actors of the
 distribution chain from manufacturers over wholesalers to retail. Indeed, in the
 report, there is few detailed consideration on the operational (and other) impact for
 the wholesale.
- Moreover, the authors of the report clearly did not take into consideration that the
 wholesale sector is completely different in every member state and operates
 accordingly in a completely different set-up.
- Whereas the manufacturers are mainly a group of **5** multi-national companies active in **all 27** member states, the wholesale business :
 - o Is mainly operated by family owned small and medium-sized companies,
 - o **merely** active in only **1** member state,
 - o and/or even in one trade segment of that one member state.
- The wholesale business is characterized by small operational entities with very limited means :
 - as well in terms of staff,
 - in technical capabilities,
 - o in know-how,
 - o in lobbying resources,
 - and financial resources.
- The limited financial resources of the wholesalers are determined by following facts:
 - there are predominantly 5 multi-national tobacco manufacturing companies, being the "strong" suppliers for the wholesalers, strongly limiting "the room for negotiation" of trade terms.
 - the retail sector is for the bigger part characterized by strong, sometimes even multi-national companies, having the choice between a number of wholesalers for their supplies and as such able to "impose" their trade terms to the wholesalers.

¹ Fetadis represents the main tobacco wholesalers active on the Belgian market. Together they represent over 80% of the Belgian market.

- the remaining part of the retail sector is characterized by a large number of small independent shops with higher financial risk and cost.
- o in countries with a tax-stamp and a predominantly "Ad valorem" tax-structure (in casu Belgium), the consumer selling price is determined by the tobacco manufacturer. This selling price includes the margin of the whole distribution chain, i.e. wholesale and retail. Thus the profitability and liveability of the wholesale business is de facto determined by the tobacco manufacturers.
- ⇒ as a result, the part of the value chain remaining with the wholesalers as gross margin is only approximately 1 % of the consumer selling price.

B) Impact T & T

Manufacturers

- In our view, the implementation of a T & T system on tobacco products can be easily implemented in the current and existing manufacturing process at limited extra cost.
- The manufacturers already do have the know-how and the expertise to implement such a system.
- Depending on the chosen option or method, this limited operational cost might only be increased by a one-time investment in some hardware, with negligible impact on the profitability of this large multi-national companies.

Retail

- Although the impression is created that retail is not impacted by T & T, as scanning is only foreseen up to the first retailer, **this is not true**. Indeed, all retailers will need to have a Global Location Number (GLN) per individual outlet / location. The cost for a GLN is composed of:
 - a one-off membership fee: estimated between 80 and 200 € per GLN, depending on the member state
 - a yearly subscription with similar costs per year
- It is very likely that many small retailers will not be able to finance this extra cost, which does not bring them any benefit, and will thus try to recover these costs from their wholesaler.

Wholesale

The wholesale process is a complex process with many different steps. Without going into details, hereby the main areas of impact :

- Validation of goods receipt (incoming goods) per manufacturer of brand and packaging
- o Re-allocation of stock over warehouse and / or picking facilities
- o Order-entry per customer

- Order-entry per GLN
- Scanning per individual delivery unit as well as packaging material during picking process
- Process T & T obligations during aggregation in picking process of both goods and packaging
- Administrative encoding of data (outgoing goods) to EU-repository
- o Process T & T obligations in transport
- o Process T & T obligations with transport documents / invoices
- GLN management: very frequent changes in name, address, legal entity, legal ownership, etc...
- Management of reverse logistics

The above mentioned impact on processes will lead to an important increase of structural costs and investments :

- Resources: extra operational activities (see above), slower processes, expensive shift work, ...
- High administrative burdens, extension of tasks, ...
- Investments in hardware and software, maintenance, ...
- Increased costs in training
- Increased costs in audit and controlling
- ⇒ Based on a first test and conservative estimate, it appears that the structural operational cost for the wholesaler (without the extra administration cost and investments) will increase by over 70 % !!!
- ⇒ The contribution of the manufacturers mentioned in option 1, is absolutely not compensating the structural extra cost nor the investments.

C) Proposed options

Since, as above mentioned, the impact of a T & T system on the wholesale business was not fully examined, it is difficult to appraise the different options.

D) Cost and Benefit analysis

As wholesale federation, it is very difficult to have an educated opinion on the benefit analysis, since the analysis is based on the choice of certain parameters and hypotheses.

Regarding the cost analysis however, we sincerely doubt that the analysis is appropriate as it does not take into account the real cost impact on the wholesale business. (See points A, B, C and E)

E) Conclusion

As wholesalers, any T & T system must respect the particularities of the wholesale business :

- o It must be operationally feasible
- o It must be global European system
- o It must be financially affordable
- o It may not increase administrative burden
- o It should actively and proven contribute to reduce illicit trade

Taking into account the already low profitability, the Belgian Wholesale Federation, Fetadis, requests that the implementation of a T & T system is done on basis of a fair and equitable sharing of the related costs between the 3 stakeholders (manufacturers – wholesale – retail)

Asbl FetaDis Vzw

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